



Clinical trial results: Immune response to COVID-19 Vaccination in people with Diabetes Mellitus - COVAC-DM study

Summary

EudraCT number	2021-001459-15
Trial protocol	AT
Global end of trial date	24 June 2022

Results information

Result version number	v1 (current)
This version publication date	15 November 2023
First version publication date	15 November 2023

Trial information

Trial identification

Sponsor protocol code	HS-2021-02
-----------------------	------------

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	-
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Medical University of Graz
Sponsor organisation address	Neue Stiftingtalstrasse 6, Graz, Austria, 8010
Public contact	Dr. Caren Sourij (Sub-Investigator), Medical University of Graz, 43 316385 78038, caren.sourij@medunigraz.at
Scientific contact	Prof. Harald Sourij, MBA (Principal Investigator), Medical University of Graz, 43 316385 81310, ha.sourij@medunigraz.at

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	30 August 2022
Is this the analysis of the primary completion data?	Yes
Primary completion date	24 June 2022
Global end of trial reached?	Yes
Global end of trial date	24 June 2022
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary objective is to investigate the short and mid-term humoral immune response to COVID-19 vaccines as assessed by anti-spike protein antibodies in people with diabetes as compared to healthy controls.

Protection of trial subjects:

physical examination at the first visit

assessment of general health status of each participant (e.g. general appearance, neck/thyroid, chest/lung., etc.)

Systolic and diastolic blood pressure (mmHg), pulse (bpm),

minimal invasive blood samples will be taken for laboratory safety variables (hematology, biochemistry coagulation, urinalysis)

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	16 April 2021
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Austria: 161
Worldwide total number of subjects	161
EEA total number of subjects	161

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0

Adults (18-64 years)	146
From 65 to 84 years	15
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Subjects will be recruited from the participant database kept at the trial site

Pre-assignment

Screening details:

Screening Visit: oral and written infos. After signing IC at the screening Visit participants will be screened for eligibility (inclusion/exclusion criteria), physical examination, Discussion of all procedures.

Period 1

Period 1 title	Antibody response (overall period)
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Arm title	Antibody response
------------------	-------------------

Arm description:

Antibody response after vaccinations

Arm type	Active comparator
Investigational medicinal product name	Comirnaty/ Spykevac/ Vaxzevria
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Injection

Dosage and administration details:

0.3 ml of the vaccine is injected into the deltoid muscle of the upper arm

Number of subjects in period 1	Antibody response
Started	161
Completed	150
Not completed	11
Consent withdrawn by subject	2
postpone vaccination	6
subjects knowingly know having COVID-19	3

Baseline characteristics

Reporting groups

Reporting group title	Antibody response
-----------------------	-------------------

Reporting group description:

18 - 80 years

Reporting group values	Antibody response	Total	
Number of subjects	161	161	
Age categorical			
18 - 64 years			
Units: Subjects			
In utero	0	0	
Preterm newborn infants (gestational age < 37 wks)	0	0	
Newborns (0-27 days)	0	0	
Infants and toddlers (28 days-23 months)	0	0	
Children (2-11 years)	0	0	
Adolescents (12-17 years)	0	0	
Adults (18-64 years)	146	146	
From 65-84 years	15	15	
85 years and over	0	0	
Gender categorical			
Male and Female			
Units: Subjects			
Female	71	71	
Male	90	90	

End points

End points reporting groups

Reporting group title	Antibody response
Reporting group description: Antibody response after vaccinations	
Subject analysis set title	T1D HbA1c \leq 58 mmol/mol
Subject analysis set type	Sub-group analysis
Subject analysis set description: Subjects with Type 1 Diabetes with a lower HbA1c under 58mmol/mol	
Subject analysis set title	T1D HbA1c $>$ 58 mmol/mol
Subject analysis set type	Sub-group analysis
Subject analysis set description: Subjects wit Type 1 Diabetes with a higher HbA1c over 58 mmol/mol	
Subject analysis set title	T2D HbA1c \leq 58 mmol/mol
Subject analysis set type	Sub-group analysis
Subject analysis set description: Subjects with Type 2 Diabetes with a lower HbA1c under 58 mmol/mol	
Subject analysis set title	T2D HbA1c $>$ 58 mmol/mol
Subject analysis set type	Sub-group analysis
Subject analysis set description: Subjects with Type 2 Diabetes with a higher HbA1c over 58 mmol/mol	

Primary: CoV-2 S Antibody level

End point title	CoV-2 S Antibody level
End point description:	
End point type	Primary
End point timeframe:	
Level of antibodies At 7 to 14 days after the first vaccination	

End point values	T1D HbA1c \leq 58 mmol/mol	T1D HbA1c $>$ 58 mmol/mol	T2D HbA1c \leq 58 mmol/mol	T2D HbA1c $>$ 58 mmol/mol
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	49	26	37	38
Units: antibody unit(s)				
arithmetic mean (standard deviation)	8696.0 (\pm 7095.8)	5822.2 (\pm 4144.5)	4204.6 (\pm 3961.7)	5804.1 (\pm 6522.9)

Statistical analyses

Statistical analysis title	Antibody response
Comparison groups	T1D HbA1c \leq 58 mmol/mol v T1D HbA1c $>$ 58 mmol/mol v T2D HbA1c \leq 58 mmol/mol v T2D HbA1c $>$ 58 mmol/mol

Number of subjects included in analysis	150
Analysis specification	Pre-specified
Analysis type	other ^[1]
P-value	< 0.05
Method	Chi-squared
Parameter estimate	Median difference (final values)
Confidence interval	
level	95 %
sides	2-sided

Notes:

[1] - Categorical variables were summarized as frequencies and percentages (%). Quantitative variables were summarized as means and standard deviations (\pm SD). Categorical variables were compared with diabetes groups using chi-squared or Fisher's exact tests, Postvaccination, side effects were compared between people with type 1 diabetes and type 2 diabetes using chi-squared or Fisher's exacts tests, multiple comparisons using post-hoc Bonferroni correction, or Wilcoxon's signed-rank test.

Adverse events

Adverse events information

Timeframe for reporting adverse events:

16. April 2021 until 31. March 2023

Assessment type	Systematic
-----------------	------------

Dictionary used

Dictionary name	MedDRA
-----------------	--------

Dictionary version	26.1
--------------------	------

Reporting groups

Reporting group title	Temperature 37-37,9 °C
-----------------------	------------------------

Reporting group description: -

Reporting group title	Temperature >38 °C
-----------------------	--------------------

Reporting group description: -

Reporting group title	injection site reaction
-----------------------	-------------------------

Reporting group description: -

Reporting group title	Swelling
-----------------------	----------

Reporting group description: -

Reporting group title	Redness
-----------------------	---------

Reporting group description: -

Reporting group title	Pain
-----------------------	------

Reporting group description: -

Reporting group title	Headache
-----------------------	----------

Reporting group description: -

Reporting group title	Fatigue
-----------------------	---------

Reporting group description: -

Reporting group title	Arthralgia
-----------------------	------------

Reporting group description: -

Reporting group title	Covid-19
-----------------------	----------

Reporting group description: -

Reporting group title	Hepatocellular Carcinoma
-----------------------	--------------------------

Reporting group description: -

Reporting group title	Hypertensive crisis
-----------------------	---------------------

Reporting group description: -

Reporting group title	Minor stroke
-----------------------	--------------

Reporting group description: -

Reporting group title	Dyspnea and oedema
-----------------------	--------------------

Reporting group description: -

Reporting group title	AV Block III
-----------------------	--------------

Reporting group description: -

Reporting group title	Urteic stones
-----------------------	---------------

Reporting group description: -

Reporting group title	Syncope
-----------------------	---------

Reporting group description: -

Reporting group title	Ovarian cyst
-----------------------	--------------

Reporting group description: -

Reporting group title	Chest pain (coronary heart disease)
-----------------------	-------------------------------------

Reporting group description: -

Reporting group title	Periradicular infiltration
-----------------------	----------------------------

Reporting group description: -	
Reporting group title	Cerebellar infarction
Reporting group description: -	
Reporting group title	NSTEMI
Reporting group description: -	
Reporting group title	Sick sinus syndrome
Reporting group description: -	
Reporting group title	Enteritis
Reporting group description: -	
Reporting group title	Acute pancreatitis
Reporting group description: -	
Reporting group title	Surgery (shoulder)
Reporting group description: -	
Reporting group title	EPU/ablation
Reporting group description: -	
Reporting group title	angina pectoris
Reporting group description: -	
Reporting group title	Elective surgery
Reporting group description: -	

Serious adverse events	Temperature 37-37,9 °C	Temperature >38 °C	injection site reaction
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Hepatocellular carcinoma			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ovarian cyst			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
AV Block III			
alternative assessment type: Non-systematic			

subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chest pain (coronary heart disease) alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NSTEMI alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sick sinus syndrome alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
EPU/ablation alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
angina pectoris alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical and medical procedures Periradikuläre Infiltration alternative assessment type: Non-systematic			

subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgery (shoulder)			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Elective surgery			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Hypertensive crisis			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
minor stroke			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebellar infarction			
alternative assessment type: Non-systematic			

subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Enteritis			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Dyspnea and oedema			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Urteic stones			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
Acute pancreatitis			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
COVID-19			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Swelling	Redness	Pain
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Hepatocellular carcinoma			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ovarian cyst			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
AV Block III			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chest pain (coronary heart disease)			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NSTEMI			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sick sinus syndrome			
alternative assessment type: Non-systematic			

subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
EPU/ablation			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
angina pectoris			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical and medical procedures			
Periradikuläre Infiltration			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgery (shoulder)			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Elective surgery			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Hypertensive crisis			
alternative assessment type: Non-systematic			

subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
minor stroke			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebellar infarction			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Enteritis			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Dyspnea and oedema			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Urteic stones			
alternative assessment type: Non-systematic			

subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
Acute pancreatitis			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
COVID-19			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Headache	Fatigue	Arthralgia
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Hepatocellular carcinoma			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ovarian cyst			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
AV Block III			
alternative assessment type: Non-systematic			

subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chest pain (coronary heart disease) alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NSTEMI alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sick sinus syndrome alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
EPU/ablation alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
angina pectoris alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical and medical procedures Periradikuläre Infiltration alternative assessment type: Non-systematic			

subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgery (shoulder)			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Elective surgery			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Hypertensive crisis			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
minor stroke			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebellar infarction			
alternative assessment type: Non-systematic			

subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Enteritis			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Dyspnea and oedema			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Urteic stones			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
Acute pancreatitis			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
COVID-19			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Covid-19	Hepatocellular Carcinoma	Hypertensive crisis
Total subjects affected by serious adverse events			
subjects affected / exposed	8 / 150 (5.33%)	1 / 150 (0.67%)	1 / 150 (0.67%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Hepatocellular carcinoma			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	1 / 150 (0.67%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ovarian cyst			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
AV Block III			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chest pain (coronary heart disease)			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NSTEMI			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sick sinus syndrome			
alternative assessment type: Non-systematic			

subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
EPU/ablation			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
angina pectoris			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical and medical procedures			
Periradikuläre Infiltration			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgery (shoulder)			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Elective surgery			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Hypertensive crisis			
alternative assessment type: Non-systematic			

subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	1 / 150 (0.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
minor stroke			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebellar infarction			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Enteritis			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Dyspnea and oedema			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Urteic stones			
alternative assessment type: Non-systematic			

subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
Acute pancreatitis			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
COVID-19			
alternative assessment type: Non-systematic			
subjects affected / exposed	8 / 150 (5.33%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Minor stroke	Dyspnea and oedema	AV Block III
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 150 (0.67%)	1 / 150 (0.67%)	1 / 150 (0.67%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Hepatocellular carcinoma			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ovarian cyst			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
AV Block III			
alternative assessment type: Non-systematic			

subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	1 / 150 (0.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chest pain (coronary heart disease) alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NSTEMI alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sick sinus syndrome alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
EPU/ablation alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
angina pectoris alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical and medical procedures Periradikuläre Infiltration alternative assessment type: Non-systematic			

subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgery (shoulder) alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Elective surgery alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Hypertensive crisis alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
minor stroke alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 150 (0.67%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebellar infarction alternative assessment type: Non-systematic			

subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Enteritis			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Dyspnea and oedema			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	1 / 150 (0.67%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Urteic stones			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
Acute pancreatitis			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
COVID-19			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Urteic stones	Syncope	Ovarian cyst
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 150 (0.67%)	1 / 150 (0.67%)	1 / 150 (0.67%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Hepatocellular carcinoma			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ovarian cyst			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	1 / 150 (0.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
AV Block III			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chest pain (coronary heart disease)			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NSTEMI			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sick sinus syndrome			
alternative assessment type: Non-systematic			

subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
EPU/ablation			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
angina pectoris			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical and medical procedures			
Periradikuläre Infiltration			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgery (shoulder)			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Elective surgery			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Hypertensive crisis			
alternative assessment type: Non-systematic			

subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
minor stroke			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	1 / 150 (0.67%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebellar infarction			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Enteritis			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Dyspnea and oedema			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Urteic stones			
alternative assessment type: Non-systematic			

subjects affected / exposed	1 / 150 (0.67%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
Acute pancreatitis			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
COVID-19			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Chest pain (coronary heart disease)	Periradicular infiltration	Cerebellar infarction
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 150 (0.67%)	1 / 150 (0.67%)	1 / 150 (0.67%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Hepatocellular carcinoma			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ovarian cyst			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
AV Block III			
alternative assessment type: Non-systematic			

subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chest pain (coronary heart disease) alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 150 (0.67%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NSTEMI alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sick sinus syndrome alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
EPU/ablation alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
angina pectoris alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical and medical procedures Periradikuläre Infiltration alternative assessment type: Non-systematic			

subjects affected / exposed	0 / 150 (0.00%)	1 / 150 (0.67%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgery (shoulder) alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Elective surgery alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Hypertensive crisis alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
minor stroke alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebellar infarction alternative assessment type: Non-systematic			

subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	1 / 150 (0.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Enteritis			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Dyspnea and oedema			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Urteic stones			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
Acute pancreatitis			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
COVID-19			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	NSTEMI	Sick sinus syndrome	Enteritis
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 150 (0.67%)	1 / 150 (0.67%)	1 / 150 (0.67%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Hepatocellular carcinoma			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ovarian cyst			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
AV Block III			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chest pain (coronary heart disease)			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NSTEMI			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 150 (0.67%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sick sinus syndrome			
alternative assessment type: Non-systematic			

subjects affected / exposed	0 / 150 (0.00%)	1 / 150 (0.67%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
EPU/ablation			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
angina pectoris			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical and medical procedures			
Periradikuläre Infiltration			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgery (shoulder)			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Elective surgery			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Hypertensive crisis			
alternative assessment type: Non-systematic			

subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
minor stroke			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebellar infarction			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Enteritis			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	1 / 150 (0.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Dyspnea and oedema			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Urteic stones			
alternative assessment type: Non-systematic			

subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
Acute pancreatitis			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
COVID-19			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Acute pancreatitis	Surgery (shoulder)	EPU/ablation
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 150 (0.67%)	1 / 150 (0.67%)	1 / 150 (0.67%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Hepatocellular carcinoma			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ovarian cyst			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
AV Block III			
alternative assessment type: Non-systematic			

subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chest pain (coronary heart disease) alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NSTEMI alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sick sinus syndrome alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
EPU/ablation alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	1 / 150 (0.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
angina pectoris alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical and medical procedures Periradikuläre Infiltration alternative assessment type: Non-systematic			

subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgery (shoulder) alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	1 / 150 (0.67%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Elective surgery alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Hypertensive crisis alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
minor stroke alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebellar infarction alternative assessment type: Non-systematic			

subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Enteritis			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Dyspnea and oedema			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Urteic stones			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
Acute pancreatitis			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 150 (0.67%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
COVID-19			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	angina pectoris	Elective surgery	
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 150 (0.67%)	2 / 150 (1.33%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Hepatocellular carcinoma			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ovarian cyst			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
AV Block III			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chest pain (coronary heart disease)			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
NSTEMI			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sick sinus syndrome			
alternative assessment type: Non-systematic			

subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
EPU/ablation			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
angina pectoris			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 150 (0.67%)	0 / 150 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Surgical and medical procedures			
Periradikuläre Infiltration			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Surgery (shoulder)			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Elective surgery			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	1 / 150 (0.67%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Hypertensive crisis			
alternative assessment type: Non-systematic			

subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
minor stroke			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Syncope			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebellar infarction			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Enteritis			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Dyspnea and oedema			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
Urteic stones			
alternative assessment type: Non-systematic			

subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endocrine disorders			
Acute pancreatitis			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
COVID-19			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Frequency threshold for reporting non-serious adverse events: 3 %

Non-serious adverse events	Temperature 37-37,9 °C	Temperature >38 °C	injection site reaction
Total subjects affected by non-serious adverse events			
subjects affected / exposed	12 / 150 (8.00%)	2 / 150 (1.33%)	104 / 150 (69.33%)
Investigations			
Injection site reaction			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	104 / 150 (69.33%)
occurrences (all)	0	0	104
Temperature 37 - 37,9			
alternative assessment type: Non-systematic			
subjects affected / exposed	12 / 150 (8.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences (all)	12	0	0
Temperature >38			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	2 / 150 (1.33%)	0 / 150 (0.00%)
occurrences (all)	0	2	0
Swelling			

alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences (all)	0	0	0
Redness			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences (all)	0	0	0
Pain			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences (all)	0	0	0
Headache			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences (all)	0	0	0
Fatigue			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences (all)	0	0	0
Arthralgia			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Swelling	Redness	Pain
Total subjects affected by non-serious adverse events			
subjects affected / exposed	16 / 150 (10.67%)	9 / 150 (6.00%)	98 / 150 (65.33%)
Investigations			
Injection site reaction			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences (all)	0	0	0
Temperature 37 - 37,9			
alternative assessment type: Non-systematic			

subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences (all)	0	0	0
Temperature >38			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences (all)	0	0	0
Swelling			
alternative assessment type: Non-systematic			
subjects affected / exposed	16 / 150 (10.67%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences (all)	16	0	0
Redness			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	9 / 150 (6.00%)	0 / 150 (0.00%)
occurrences (all)	0	9	0
Pain			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	98 / 150 (65.33%)
occurrences (all)	0	0	98
Headache			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences (all)	0	0	0
Fatigue			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences (all)	0	0	0
Arthralgia			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Headache	Fatigue	Arthralgia
Total subjects affected by non-serious adverse events			
subjects affected / exposed	33 / 150 (22.00%)	45 / 150 (30.00%)	15 / 150 (10.00%)

Investigations			
Injection site reaction			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences (all)	0	0	0
Temperature 37 - 37,9			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences (all)	0	0	0
Temperature >38			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences (all)	0	0	0
Swelling			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences (all)	0	0	0
Redness			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences (all)	0	0	0
Pain			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences (all)	0	0	0
Headache			
alternative assessment type: Non-systematic			
subjects affected / exposed	33 / 150 (22.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences (all)	33	0	0
Fatigue			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	45 / 150 (30.00%)	0 / 150 (0.00%)
occurrences (all)	0	45	0
Arthralgia			
alternative assessment type: Non-systematic			

subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	15 / 150 (10.00%)
occurrences (all)	0	0	15

Non-serious adverse events	Covid-19	Hepatocellular Carcinoma	Hypertensive crisis
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
Investigations			
Injection site reaction			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences (all)	0	0	0
Temperature 37 - 37,9			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences (all)	0	0	0
Temperature >38			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences (all)	0	0	0
Swelling			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences (all)	0	0	0
Redness			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences (all)	0	0	0
Pain			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences (all)	0	0	0
Headache			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences (all)	0	0	0

Fatigue			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences (all)	0	0	0
Arthralgia			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Minor stroke	Dyspnea and oedema	AV Block III
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
Investigations			
Injection site reaction			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences (all)	0	0	0
Temperature 37 - 37,9			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences (all)	0	0	0
Temperature >38			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences (all)	0	0	0
Swelling			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences (all)	0	0	0
Redness			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences (all)	0	0	0
Pain			
alternative assessment type: Non-systematic			

subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences (all)	0	0	0
Headache			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences (all)	0	0	0
Fatigue			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences (all)	0	0	0
Arthralgia			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Urteic stones	Syncope	Ovarian cyst
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
Investigations			
Injection site reaction			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences (all)	0	0	0
Temperature 37 - 37,9			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences (all)	0	0	0
Temperature >38			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences (all)	0	0	0
Swelling			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences (all)	0	0	0

Redness			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences (all)	0	0	0
Pain			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences (all)	0	0	0
Headache			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences (all)	0	0	0
Fatigue			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences (all)	0	0	0
Arthralgia			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Chest pain (coronary heart disease)	Periradicular infiltration	Cerebellar infarction
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
Investigations			
Injection site reaction			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences (all)	0	0	0
Temperature 37 - 37,9			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences (all)	0	0	0
Temperature >38			
alternative assessment type: Non-systematic			

subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences (all)	0	0	0
Swelling			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences (all)	0	0	0
Redness			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences (all)	0	0	0
Pain			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences (all)	0	0	0
Headache			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences (all)	0	0	0
Fatigue			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences (all)	0	0	0
Arthralgia			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	NSTEMI	Sick sinus syndrome	Enteritis
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
Investigations			
Injection site reaction			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences (all)	0	0	0

Temperature 37 - 37,9			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences (all)	0	0	0
Temperature >38			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences (all)	0	0	0
Swelling			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences (all)	0	0	0
Redness			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences (all)	0	0	0
Pain			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences (all)	0	0	0
Headache			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences (all)	0	0	0
Fatigue			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences (all)	0	0	0
Arthralgia			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Acute pancreatitis	Surgery (shoulder)	EPU/ablation
Total subjects affected by non-serious adverse events			

subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
Investigations			
Injection site reaction			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences (all)	0	0	0
Temperature 37 - 37,9			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences (all)	0	0	0
Temperature >38			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences (all)	0	0	0
Swelling			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences (all)	0	0	0
Redness			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences (all)	0	0	0
Pain			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences (all)	0	0	0
Headache			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences (all)	0	0	0
Fatigue			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences (all)	0	0	0
Arthralgia			

alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	angina pectoris	Elective surgery	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	
Investigations			
Injection site reaction			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	
occurrences (all)	0	0	
Temperature 37 - 37,9			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	
occurrences (all)	0	0	
Temperature >38			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	
occurrences (all)	0	0	
Swelling			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	
occurrences (all)	0	0	
Redness			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	
occurrences (all)	0	0	
Pain			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	
occurrences (all)	0	0	
Headache			
alternative assessment type: Non-systematic			

subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	
occurrences (all)	0	0	
Fatigue			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	
occurrences (all)	0	0	
Arthralgia			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	
occurrences (all)	0	0	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported

Online references

<http://www.ncbi.nlm.nih.gov/pubmed/34984802>