Clinical trial results:
Effects of continuous exercise on time spent in euglycemia and inflammation under the treatment of insulin degludec in patients with type 1 diabetes – a crossover, randomized trial (InflamEx)

Summary

EudraCT number	2017-000922-37
Trial protocol	AT
Global end of trial date	16 May 2018

Results information

Result version number	v1 (current)
This version publication date	05 January 2024
First version publication date	05 January 2024

Trial information

Trial identification

Sponsor protocol code	InflamEX

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,
Public contact	Harald Kojzar (Project Coordinator), Medical University of Graz, harald.kojzar@medunigraz.at
Scientific contact	Prof. Dr. Harald Sourij (Principal Investigator), Medical University of Graz, 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	26 April 2018
Is this the analysis of the primary completion data?	Yes
Primary completion date	26 April 2018
Global end of trial reached?	Yes
Global end of trial date	16 May 2018
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Difference in mean time in euglycemia 24 hours after exercise

Protection of trial subjects:

ethical standards were followed, the trial adhere to strict ethical standards to ensure that participants were treated fairly and with respect protecting the privacy and confidentiality of participants education and training in protection of clinical trials participants for all study team members

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	18 September 2017
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: 10
Worldwide total number of subjects	10
EEA total number of subjects	10

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)	10
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Study participants were recruited using the subject database of our department

Pre-assignment

Screening details:

- Informed consent
- Inclusion/Exclusion criteria
- Demography
- Participants diabetes history, current insulin therapy
- Medical history, concomitant illness
- Body measurements and vital signs
- ECG
- HbA1c measurement

Period 1

Period 1 title	Baseline
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Arm title	Baseline
Arm description: -	
Arm type	Baseline
Investigational medicinal product name	Insulin Degludec
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Injection

Dosage and administration details:

Insulin Degludec administrated according to the investigator

Number of subjects in period 1	Baseline
Started	10
Completed	10

Period 2	
Period 2 title	Intervention period
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms	
Are arms mutually exclusive?	Yes
Arm title	100% Degudec

Arm description: -

Arm type	Active comparator
Investigational medicinal product name	Insulin Degludec
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Injection

Dosage and administration details:

Insulin Degludec 100% as told by the investigator

Arm title	75% Degludec

Arm description: -

Arm type	Active comparator
Investigational medicinal product name	Insulin Degludec
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Injection

Dosage and administration details:

Insulin Degludec 75% as told by the investigator

Number of subjects in period 2	100% Degudec	75% Degludec
Started	5	5
Completed	5	4
Not completed	0	1
Consent withdrawn by subject	-	1

Baseline characteristics

Reporting groups	
Reporting group title	Baseline

Reporting group description: -

Reporting group values	Baseline	Total	
Number of subjects	10	10	
Age categorical 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)	10	10	
From 65-84 years	0	0	
85 years and over	0	0	
Age continuous Units: years			
arithmetic mean	32.1		
standard deviation	± 9.0	-	
Gender categorical Units: Subjects			
Female	4	4	
Male	6	6	

End points

End points reporting groups

Reporting group title	Baseline
Reporting group description: -	
Reporting group title	100% Degudec
Reporting group description: -	
Reporting group title	75% Degludec
Reporting group description: -	

Primary: Difference in mean time in euglycemia 24 hours after exercise

End point title	Difference in mean time in euglycemia 24 hours after exercise
End point description:	
End point type	Primary
End point timeframe:	
2 weeks (1 week per group)	

End point values	100% Degudec	75% Degludec		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	5	4		
Units: hours				
arithmetic mean (standard deviation)	57 (± 14)	62 (± 15)		

Statistical analyses

Statistical analysis title	Crossover Trial Analysis
Comparison groups	100% Degudec v 75% Degludec
Number of subjects included in analysis	9
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.04
Method	ANOVA

Secondary: Numbers of confirmed hypoglycemic episodes during exercise (< 4.4 mmol/l

End point title	Numbers of confirmed hypoglycemic episodes during exercise (< 4.4 mmol/l
End point description:	
End point type	Secondary

End point timeframe:

2 tweeks of training during the one hour exercise per day

End point values	100% Degudec	75% Degludec		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	5	4		
Units: Hypo´s (blood sugar below 4,4 mmol/l)	0	0		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Adverse event date was collected from 25.Oct.2017 (first patient first visit) until 02.Mar.2018 (last patient last visit).

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	26.0

Reporting groups

Reporting group title	75% Degludec

Reporting group description: -

Serious adverse events	75% Degludec		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 1 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		

Frequency threshold for reporting non-serious adverse events: 5 %

Non-serious adverse events	75% Degludec		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	1 / 1 (100.00%)		
Infections and infestations			
Nasopharyngitis			
subjects affected / exposed	1 / 1 (100.00%)		
occurrences (all)	1		

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