Clinical trial results:
Invloed van Somatuline® autogel 120mg op post-operatieve drainage na rectumresectie voor rectumcarcinoom

Summary

EudraCT number	2010-022572-32
Trial protocol	BE
Global end of trial date	31 December 2014

Results information

Result version number	v1 (current)
This version publication date	04 December 2024
First version publication date	04 December 2024

Trial information

Trial identification

Sponsor protocol code	AGO/2010/005 (A-48-52030-740)

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	University Hospital Ghent
Sponsor organisation address	C. Heymanslaan, Ghent, Belgium, 9000
Public contact	Trial Bureau, Ghent University Hospital, 32 93320530, hiruz.ctu@uzgent.be
Scientific contact	Trial Bureau, Ghent University Hospital, 32 93320530, hiruz.ctu@uzgent.be

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	31 December 2014
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	31 December 2014
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Nagaan van het effect van een éénmalige diep onderhuidse injectie met Somatuline® autogel 120 mg op de productie van drainvocht postoperatief.

Protection of trial subjects:

If the subjects are not under 24-hour supervision of the investigator or his/her staff (out-patients, volunteers), they (or their designee, if appropriate) must be provided with a "trial card" indicating the name of the investigational product, the trial number, the investigator's name and a 24-hour emergency contact number.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	18 April 2011
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	Belgium: 24
Worldwide total number of subjects	24
EEA total number of subjects	24

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)	24
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

NAP

Pre-assignment

Screening details:

NAP

Period 1

Period 1 title	Overal Study (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Monitor, Assessor

Arms

Are arms mutually exclusive?	Yes
Arm title	Somatuline

Arm description: -

Arm type	Active comparator
Investigational medicinal product name	Somatuline
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Injection

Dosage and administration details:

Het doel van deze studie is na te gaan wat het effect is van een éénmalige diep onderhuidse injectie met Somatuline® autogel 120 mg versus een éénmalige diep onderhuidse placebo-injectie, op de productie van drainvocht postoperatief

Arm title	Placebo

Arm description:

placebo-injectie met natriumchloride 0.9%

Arm type	Placebo
Investigational medicinal product name	natriumchloride
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Injection

Dosage and administration details:

natriumchloride 0.9%

Number of subjects in period 1	Somatuline	Placebo
Started	12	12
Completed	12	12

Baseline characteristics

End points

End points reporting groups

Reporting group title	Somatuline
Reporting group description: -	
Reporting group title	Placebo
Reporting group description:	
placebo-injectie met natriumchloride 0.9%	

Primary: Primary

End point title	Primary[1]
End point description:	
Het doel van deze studie is na te gaan wat het effect is van een éénmalige diep onderhuidse injectie met Somatuline® autogel 120 mg versus een éénmalige diep onderhuidse placebo-injectie, op de productie van drainvocht postoperatief.	
End point type	Primary
End point timeframe:	
during the study	

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: NAP

End point values	Somatuline	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	12	12		
Units: units	12	12		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]	
Timeframe for reporting adverse events:	
During the study	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	0

Frequency threshold for reporting non-serious adverse events: 0 %

Notes:

[1] - There are no non-serious adverse events recorded for these results. It is expected that there will be at least one non-serious adverse event reported.
Justification: NAP

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