Clinical trial results:
Wound Management in Post-Bariatric Surgery
Investigation for the reduction of the mean drainage volume in patients after abdominoplasty / lower body lift using Artiss Fibrin Sealant in comparison to the standard procedure

Summary

EudraCT number	2013-004353-24
Trial protocol	DE
Global end of trial date	03 March 2017

Results information

Result version number	v1 (current)
This version publication date	09 August 2020
First version publication date	09 August 2020
Summary attachment (see zip file)	Synopsis WMPS (WMPS_Ergebnisbericht_AMG_final1.0_2017-07-03.pdf)

Trial information

Trial identification

Sponsor protocol code	WMPS

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	-
WHO universal trial number (UTN)	-
Other trial identifiers	DRKS: DRKS00011036

Notes:

Sponsors

Sponsor organisation name	Universität Leipzig
Sponsor organisation address	Ritterstr. 26, Leipzig, Germany, 04109
Public contact	IFB Adipositas Data Center, Universität Leipzig, ZKS Leipzig, christiane.prettin@zks.uni-leipzig.de
Scientific contact	IFB Adipositas Data Center, Universität Leipzig, ZKS Leipzig, christiane.prettin@zks.uni-leipzig.de

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	03 July 2017
Is this the analysis of the primary completion data?	Yes
Primary completion date	03 March 2017
Global end of trial reached?	Yes
Global end of trial date	03 March 2017
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

The aim of the trial is to assess the effectiveness of the Artiss™ fibrin sealant compared to the standard technique in reducing the volume of wound drainage fluid in patients that have undergone a planned post-bariatric body contouring operation.
The primary endpoint in the volume of wound drainage fluid.

Protection of trial subjects:

Patients observed closely for AE and SAE

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	08 August 2014
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	Germany: 18
Worldwide total number of subjects	18
EEA total number of subjects	18

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)	16
From 65 to 84 years	2
85 years and over	0

Subject disposition

Recruitment
Recruitment details: -

Pre-assignment
Screening details: There was no screening period.

Period 1	
Period 1 title	overall Trial (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Single blind
Roles blinded	Subject
Arms	
Are arms mutually exclusive?	Yes
Arm title	Artiss fibrin sealant
Arm description: -	
Arm type	Experimental
Investigational medicinal product name	Artiss
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Sealant
Routes of administration	Subcutaneous use
Dosage and administration details: 91 mg/ml milligram(s)/millilitre	
Arm title	Standard of Care
Arm description: -	
Arm type	standard of care
No investigational medicinal product assigned in this arm	

Number of subjects in period 1	Artiss fibrin sealant	Standard of Care
Started	8	10
Completed	8	10

Baseline characteristics

End points

End points reporting groups

Reporting group title	Artiss fibrin sealant
Reporting group description: -	
Reporting group title	Standard of Care
Reporting group description: -	

Primary: efficacy of artiss

End point title	efficacy of artiss[1]
End point description: draining volume during hospitalisation	
End point type	Primary
End point timeframe: periprocedural	

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: For statistical analysis please see the attached trial synopsis.

End point values	Artiss fibrin sealant	Standard of Care		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	8	10		
Units: whole	8	10		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]	
Timeframe for reporting adverse events: from surgery to end of study	
Adverse event reporting additional description: not recorded	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	18.1

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

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: For details regarding (S)AEs please see the attached trial synopsis.

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
21 August 2015	- change of PI and deputys - extension of recruitment period - specification of procedure of drainage

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported