



Clinical trial results:

Lipofilling with MSC enriched fat, a permanent autologous filler?

Summary

EudraCT number	2010-023006-12
Trial protocol	DK
Global end of trial date	16 March 2017

Results information

Result version number	v1 (current)
This version publication date	29 May 2020
First version publication date	29 May 2020

Trial information

Trial identification

Sponsor protocol code	2010-023006-12
-----------------------	----------------

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Rigshospitalet
Sponsor organisation address	Blegdamsvej 9, Copenhagen East, Denmark, 2100
Public contact	Stig-Frederik Trojahn Kølle, Rigshospitalet, Copenhagen University Hospital, stigfrederik@gmail.com
Scientific contact	Stig-Frederik Trojahn Kølle, Rigshospitalet, Copenhagen University Hospital, stigfrederik@gmail.com

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	01 October 2012
Is this the analysis of the primary completion data?	Yes
Primary completion date	16 July 2012
Global end of trial reached?	Yes
Global end of trial date	16 March 2017
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The objective of this clinical trial, is to establish a reproducible and safe method for fat transplantation, that can be used for larger reconstructions.

Fat grafts after transplantation will be examined, the residual volume will be evaluated by MR. MSC enriched fat vs. non-MSC enriched fat (control) will be tested.

Protection of trial subjects:

All subjects received informed consent both before, during and after the surgical procedures and upon follow-up. All subjects were submitted to the Department of Plastic Surgery and Burns and received sufficient pain management. All subjects also received relevant clinical follow-up's and they had the possibility to contact the responsible doctor round the clock during the trial period.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	06 January 2011
Long term follow-up planned	Yes
Long term follow-up rationale	Ethical reason, Regulatory reason, Safety, Scientific research
Long term follow-up duration	5 Years
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Denmark: 13
Worldwide total number of subjects	13
EEA total number of subjects	13

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)	13
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Subject were recruited through local advertisement at Rigshospitalet and on the danish web page forsoegsperson.dk

Pre-assignment

Screening details:

Only healthy subjects were enrolled

Pre-assignment period milestones

Number of subjects started	13
Number of subjects completed	13

Period 1

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

Arms

Are arms mutually exclusive?	No
Arm title	ASCs enriched fat grafts

Arm description:

ASC-enriched fat graft survival vs. the survival of non-enriched fat grafts

Arm type	Active comparator
Investigational medicinal product name	Ex-vivo expanded ASCs
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

600 x 10⁶ ASCs mixed with 26 ml adipose tissue = 30 ml total volume. The solution was injected subcutaneously to the back of the upper arm.

Arm title	Control - non-enriched fat grafts
------------------	-----------------------------------

Arm description: -

Arm type	Active comparator
Investigational medicinal product name	Control fat grafts
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Subdermal use

Dosage and administration details:

Pure fat graft

Number of subjects in period 1	ASCs enriched fat grafts	Control - non-enriched fat grafts
Started	13	13
Completed	10	10
Not completed	3	3
Protocol deviation	3	3

Baseline characteristics

Reporting groups

Reporting group title	Overall trial
Reporting group description:	
Healthy young subjects	

Reporting group values	Overall trial	Total	
Number of subjects	13	13	
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)	13	13	
From 65-84 years	0	0	
85 years and over	0	0	
Age continuous			
Units: years			
arithmetic mean	28.4		
full range (min-max)	22.0 to 34.8	-	
Gender categorical			
Units: Subjects			
Female	11	11	
Male	2	2	
BMI			
Units: kg/m2			
arithmetic mean	24.7		
full range (min-max)	23.3 to 26.1	-	

Subject analysis sets

Subject analysis set title	Volume retention
Subject analysis set type	Full analysis

Subject analysis set description:

Both the ASC-enriched fat grafts and the non-enriched control grafts were measured by MRI and after excision by histological examination.

Reporting group values	Volume retention		
Number of subjects	10		
Age categorical			
Units: Subjects			
In utero	0		
Preterm newborn infants (gestational age < 37 wks)	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 65-84 years	0		
85 years and over	0		
Age continuous			
Units: years			
arithmetic mean	28.4		
full range (min-max)	22.0 to 34.8		
Gender categorical			
Units: Subjects			
Female	9		
Male	1		
BMI			
Units: kg/m2			
arithmetic mean	24.7		
full range (min-max)	23.3 to 26.1		

End points

End points reporting groups

Reporting group title	ASCs enriched fat grafts
Reporting group description: ASC-enriched fat graft survival vs. the survival of non-enriched fat grafts	
Reporting group title	Control - non-enriched fat grafts
Reporting group description: -	
Subject analysis set title	Volume retention
Subject analysis set type	Full analysis
Subject analysis set description: Both the ASC-enriched fat grafts and the non-enriched control grafts were measured by MRI and after excision by histological examination.	

Primary: MRI volume measurement

End point title	MRI volume measurement
End point description:	
End point type	Primary
End point timeframe: 121 days	

End point values	ASCs enriched fat grafts	Control - non-enriched fat grafts	Volume retention	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	10	10	20	
Units: cm3				
arithmetic mean (confidence interval 95%)	23.00 (20.57 to 25.43)	4.66 (3.16 to 6.16)	23.00 (20.57 to 25.43)	

Statistical analyses

Statistical analysis title	Paired T-test
Comparison groups	ASCs enriched fat grafts v Control - non-enriched fat grafts
Number of subjects included in analysis	20
Analysis specification	Pre-specified
Analysis type	superiority
P-value	≤ 0.05
Method	t-test, 2-sided
Parameter estimate	Mean difference (final values)
Confidence interval	
level	95 %
sides	2-sided

Adverse events

Adverse events information

Timeframe for reporting adverse events:

5 years

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

Dictionary used

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

Dictionary version	18
--------------------	----

Reporting groups

Reporting group title	Treated subjects
-----------------------	------------------

Reporting group description: -

Serious adverse events	Treated subjects		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 10 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		

Frequency threshold for reporting non-serious adverse events: 1 %

Non-serious adverse events	Treated subjects		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	10 / 10 (100.00%)		
Surgical and medical procedures			
Swelling	Additional description: Temporary bruising and swelling post OP after a liposuction and lipo-injection procedure was expected and observed in all subjects.		
subjects affected / exposed	10 / 10 (100.00%)		
occurrences (all)	10		

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