Clinical trial results:
The value of a High-Volume Image-Guided Injections (HVIGI) in chronic midportion Achilles tendinopathy: a double-blind, placebo-controlled, randomised clinical trial

Summary

EudraCT number	2015-000180-13
Trial protocol	NL
Global end of trial date	16 July 2019

Results information

Result version number	v1 (current)
This version publication date	05 December 2021
First version publication date	05 December 2021
Summary attachment (see zip file)	Publication article BMJ (Effectiveness HVI in AT_BMJ.pdf)

Trial information

Trial identification

Sponsor protocol code	HAT1

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02996409
WHO universal trial number (UTN)	-
Other trial identifiers	Nederlands Trialregister (NTR): TC = 4916

Notes:

Sponsors

Sponsor organisation name	Erasmus University Medical Center
Sponsor organisation address	Dr. Molewaterplein 40, Rotterdam, Netherlands, 3015 GD
Public contact	Afdeling Sportgeneeskunde, Haaglanden Medisch Centrum, 0031 70357 42 35,
Scientific contact	Afdeling Sportgeneeskunde, Haaglanden Medisch Centrum, 0031 70357 42 35,

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 July 2019
Is this the analysis of the primary completion data?	Yes
Primary completion date	16 July 2019
Global end of trial reached?	Yes
Global end of trial date	16 July 2019
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To investigate the value of High-Volume Image-Guided Injections in patiënts with chronic midportion Achilles tendinopathy.

Protection of trial subjects:

Via ethical committee

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 June 2015
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	Netherlands: 80
Worldwide total number of subjects	80
EEA total number of subjects	80

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)	80
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

In detail described in publication

Pre-assignment

Screening details:

In detail described in publication

Period 1

Period 1 title	December 2016 to January 2019 (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Arms

Are arms mutually exclusive?	Yes
Arm title	high volume injection without corticosteroids

Arm description: -

Arm type	Experimental
Investigational medicinal product name	Saline +lidocain 40 cc
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Injection

Dosage and administration details:

Described in detail in publication

Arm title	low-volume saline injection

Arm description: -

Arm type	Placebo
Investigational medicinal product name	Saline +lidocain 2 cc
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Injection

Dosage and administration details:

Described in detail in publication

Number of subjects in period 1	high volume injection without corticosteroids	low-volume saline injection
Started	39	41
Completed	38	41
Not completed	1	0
Lost to follow-up	1	-

Baseline characteristics

Reporting groups	
Reporting group title	high volume injection without corticosteroids
Reporting group description: -	
Reporting group title	low-volume saline injection
Reporting group description: -	

Reporting group values	high volume injection without corticosteroids	low-volume saline injection	Total
Number of subjects	39	41	80
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	39	41	80
From 65-84 years	0	0	0
85 years and over	0	0	0
Age continuous Units: years			
least squares mean	46.9	48.9	
standard deviation	± 8.1	± 9.9	-
Gender categorical Units: Subjects			
Female	22	19	41
Male	17	22	39

End points

End points reporting groups	
Reporting group title	high volume injection without corticosteroids
Reporting group description: -	
Reporting group title	low-volume saline injection
Reporting group description: -	

Primary: VISA-A score	
End point title	VISA-A score
End point description:	
End point type	Primary
End point timeframe:	
24 weeks	

End point values	high volume injection without corticosteroids	low-volume saline injection		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	38	41		
Units: score 0-100	38	41		

Statistical analyses

Statistical analysis title	SAP
Statistical analysis description:	
Described in detail in the publication and the protocol of the study	
Comparison groups	low-volume saline injection v high volume injection without corticosteroids
Number of subjects included in analysis	79
Analysis specification	Pre-specified
Analysis type	non-inferiority
P-value	< 0.05
Method	GEE

Adverse events

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

Dictionary used	
Dictionary name	regular follow-up
Dictionary version	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: No adverse events

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
08 February 2016	Described in detail in the publication

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? Yes

Date	Interruption	Restart date
28 January 2016	Described in detail in the publication	-

Notes:

Limitations and caveats

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

Described in detail in the publication

Notes:

Online references

http://www.ncbi.nlm.nih.gov/pubmed/33315586