



Clinical trial results:

Influence of muscle specific activation on regional glucose uptake in the human Achilles tendon

Summary

EudraCT number	2004-004215-35
Trial protocol	FI
Global end of trial date	31 December 2009

Results information

Result version number	v1 (current)
This version publication date	24 January 2025
First version publication date	24 January 2025
Summary attachment (see zip file)	Scientific report (bojsen-møller-et-al-2006-low-intensity-tensile-loading-increases-intratendinous-glucose-uptake-in-the-achilles-tendon.pdf)

Trial information

Trial identification

Sponsor protocol code	TENPET
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Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Turku PET Centre/University of Turku
Sponsor organisation address	Kiinamylynkatu 4-8, Turku, Finland, 20540
Public contact	Kari Kalliokoski, University of Turku, +358 405145437, kari.kalliokoski@tyks.fi
Scientific contact	Kari Kalliokoski, University of Turku, +358 405145437, kari.kalliokoski@tyks.fi

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	20 January 2006
Is this the analysis of the primary completion data?	Yes
Primary completion date	10 January 2006
Global end of trial reached?	Yes
Global end of trial date	31 December 2009
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The purpose of the present study is to investigate whether isolated activation (via electrical stimulation) of an individual triceps surae muscle (medial gastrocnemius) results in region specific activity at the level of the free tendon.

Protection of trial subjects:

Hospital protection

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	07 March 2005
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	Finland: 6
Worldwide total number of subjects	6
EEA total number of subjects	6

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)	6
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Advertisement at the University

Pre-assignment

Screening details:

Blood samples

Pre-assignment period milestones

Number of subjects started	6
Number of subjects completed	6

Period 1

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

Arms

Arm title	Test leg rest
Arm description: -	
Arm type	Experimental
Investigational medicinal product name	18F-FDG
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Intravenous bolus use

Dosage and administration details:

185 MBq

Number of subjects in period 1	Test leg rest
Started	6
Completed	6

Baseline characteristics

End points

End points reporting groups

Reporting group title	Test leg rest
Reporting group description: -	

Primary: Glucose uptake

End point title	Glucose uptake ^[1]
End point description:	

End point type	Primary
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End point timeframe:

One measurement

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: See the full paper

End point values	Test leg rest			
Subject group type	Reporting group			
Number of subjects analysed	6			
Units: index				
arithmetic mean (standard deviation)	0.09 (± 0.02)			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information^[1]

Timeframe for reporting adverse events:

No adverse events

Assessment type	Non-systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	2
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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 non-serious adverse event happened

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