Clinical trial results:
The Effects of Inorganic Nitrite on cardiac and skeletal muscle: Physiology, Pharmacology and Therapeutic Potential. Peripheral Arterial Disease

Summary

EudraCT number	2012-000201-72
Trial protocol	GB
Global end of trial date	

Results information

Result version number	v1 (current)
This version publication date	
First version publication date	

Trial information

Trial identification

Sponsor protocol code	1

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	-
WHO universal trial number (UTN)	-
Other trial identifiers	Professor M.P. Frenneaux: Nitrite Study

Notes:

Sponsors

Sponsor organisation name	Grampian Healthboard
Sponsor organisation address	2 Eday Road, Summerfield House, Aberdeen, United Kingdom,
Public contact	Professor Frenneaux, NHS Grampian, - 01224437073, researchgovernance@abdn.ac.uk
Scientific contact	Professor Frenneaux, NHS Grampian, - 01224437073, researchgovernance@abdn.ac.uk
Sponsor organisation name	University of Aberdeen
Sponsor organisation address	University Office, Kings College, Regent Walk, Aberdeen, United Kingdom,
Public contact	Frenneaux, University of Aberdeen, 01224 437970, m.p.frenneaux@abdn.ac.uk
Scientific contact	Frenneaux, University of Aberdeen, 01224 437970, m.p.frenneaux@abdn.ac.uk

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	Interim
Date of interim/final analysis	29 May 2012
Is this the analysis of the primary completion data?	No
Global end of trial reached?	No

Notes:

General information about the trial

Main objective of the trial:

Primary objective: to determine the effect of inorganic Sodium Nitrate (daily dose of 7mmol) for six weeks compared to placebo in respect of:
1) treadmill absolute walking distance.
2) and quality of life in patients with stable intermittent claudication

and in a subgroup of 20 patients:
4) Skeletal muscle perfusion will be assessed using MRI
5) Skeletal muscle biopsies will be taken to assess mitochondrial function

Protection of trial subjects:

Study was withdrawn during set-up.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 May 2012
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

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)	0
From 65 to 84 years	0

85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Study was withdrawn during set-up

Period 1

Period 1 title	Study was withdrawn during set-up (overall period)
Is this the baseline period?	No
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Baseline characteristics

End points

End points reporting groups

Subject analysis set title	Study was withdrawn during set-up
Subject analysis set type	Per protocol
Subject analysis set description: Study was withdrawn during set-up	

Adverse events

Adverse events information	
Timeframe for reporting adverse events:	
Study was withdrawn during set-up	
Assessment type	

Dictionary used	
Dictionary name	N/A
Dictionary version	0

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