Clinical trial results:
Multicentre, randomized, double-blind, placebo-controlled clinical trial to evaluate the short-term efficacy and safety of two different treatment regimens of Betamethasone valerate 2.25 mg medicated plaster in patients with chronic tendinopathies of the upper and lower limbs

Summary

EudraCT number	2012-005030-11
Trial protocol	IT
Global end of trial date	24 April 2014

Results information

Result version number	v1 (current)
This version publication date	13 July 2019
First version publication date	13 July 2019

Trial information

Trial identification

Sponsor protocol code	12I-BMT08

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	IBSA Institut Biochimique SA
Sponsor organisation address	via del Piano 29, Pambio-Noranco, Switzerland,
Public contact	Stefano Rovati, IBSA Institut Biochimique SA, +41 583600000, stefano.rovati@ibsa.ch
Scientific contact	Stefano Rovati, IBSA Institut Biochimique SA, +41 583600000, stefano.rovati@ibsa.ch

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	08 June 2015
Is this the analysis of the primary completion data?	Yes
Primary completion date	06 February 2014
Global end of trial reached?	Yes
Global end of trial date	24 April 2014
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary objective of this study is to investigate the ability of betamethasone valerate 2.25 mg medicated plaster, as compared to placebo plaster (same formulation but without active ingredient), to reduce pain when topically applied daily, according to two different dose regimens (i.e., 12 or 24 hours of application/day), and during a period of 4 weeks, in patients suffering from chronic lateral elbow tendinopathy and chronic midportion Achilles tendinopathy.

Protection of trial subjects:

In case of insufficient pain relief, patients were allowed to take paracetamol 500 mg oral tablet as rescue medication, up to a maximum daily dose of 4 g.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 April 2013
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	Italy: 102
Worldwide total number of subjects	102
EEA total number of subjects	102

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)	95
From 65 to 84 years	7
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Study Initiation Date: (First Patient First Visit) 24 Apr 2013
Study Completion Date: (Last Patient Last Visit) 06 Feb 2014

Pre-assignment

Screening details:

Patients suffering from ≥12 weeks of either from Chronic Lateral Elbow Tendinopathy or Chronic Midportion (or non-insertional) Achilles Tendinopathy in their symptomatic phase, defined as a pain ≥ 50 mm on a 0-100 mm VAS as perceived when performing a standardized movement

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	BMV plaster 24h

Arm description: -

Arm type	Experimental
Investigational medicinal product name	BMV plaster 24h
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Medicated plaster
Routes of administration	Topical use

Dosage and administration details:

One single plaster was topically applied once a day for 24 hours

Arm title	BMV plaster 12h

Arm description: -

Arm type	Experimental
Investigational medicinal product name	BMV plaster 12h
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Medicated plaster
Routes of administration	Topical use

Dosage and administration details:

One single plaster was topically applied once a day for 12 hours

Arm title	PBO plaster

Arm description: -

Arm type	Placebo
Investigational medicinal product name	PBO plaster
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Medicated plaster
Routes of administration	Topical use

Dosage and administration details:
One single plaster was topically applied once a day for 12 or 24 hours

Number of subjects in period 1	BMV plaster 24h	BMV plaster 12h	PBO plaster
Started	37	32	33
Completed	35	32	29
Not completed	2	0	4
Consent withdrawn by subject	1	-	-
Adverse event, non-fatal	1	-	2
Lack of efficacy	-	-	1
Protocol deviation	-	-	1

Baseline characteristics

Reporting groups	
Reporting group title	BMV plaster 24h
Reporting group description: -	
Reporting group title	BMV plaster 12h
Reporting group description: -	
Reporting group title	PBO plaster
Reporting group description: -	

Reporting group values	BMV plaster 24h	BMV plaster 12h	PBO plaster
Number of subjects	37	32	33
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)	32	30	32
From 65-84 years	5	2	1
85 years and over	0	0	0
Gender categorical Units: Subjects			
Female	17	12	19
Male	20	20	14

Reporting group values	Total		
Number of subjects	102		
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)	94		
From 65-84 years	8		
85 years and over	0		
Gender categorical Units: Subjects			
Female	48		
Male	54		

End points

End points reporting groups	
Reporting group title	BMV plaster 24h
Reporting group description: -	
Reporting group title	BMV plaster 12h
Reporting group description: -	
Reporting group title	PBO plaster
Reporting group description: -	

Primary: VAS Pain Reduction	
End point title	VAS Pain Reduction
End point description:	
End point type	Primary
End point timeframe:	
decrease of VAS Pain score (mm) from baseline to Day 28	

End point values	BMV plaster 24h	BMV plaster 12h	PBO plaster	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	37	32	33	
Units: millimeter(s)				
arithmetic mean (standard deviation)	38.89 (± 29.80)	37.47 (± 28.09)	20.97 (± 23.27)	

Statistical analyses

Statistical analysis title	Primary Endpoint
Comparison groups	BMV plaster 24h v BMV plaster 12h v PBO plaster
Number of subjects included in analysis	102
Analysis specification	Pre-specified
Analysis type	superiority
P-value	≤ 0.05
Method	ANCOVA

Adverse events

Adverse events information	
Timeframe for reporting adverse events:	
Adverse Events were evaluated at each visit.	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	16.1

Reporting groups	
Reporting group title	BMV plaster 24h
Reporting group description: -	
Reporting group title	BMV plaster 12h
Reporting group description: -	
Reporting group title	PBO plaster
Reporting group description: -	

Serious adverse events	BMV plaster 24h	BMV plaster 12h	PBO plaster
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 37 (0.00%)	0 / 32 (0.00%)	2 / 33 (6.06%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Nervous system disorders			
Transverse sinus thrombosis			
subjects affected / exposed	0 / 37 (0.00%)	0 / 32 (0.00%)	1 / 33 (3.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Rash			
subjects affected / exposed	0 / 37 (0.00%)	0 / 32 (0.00%)	1 / 33 (3.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Frequency threshold for reporting non-serious adverse events: 0 %

Non-serious adverse events	BMV plaster 24h	BMV plaster 12h	PBO plaster
Total subjects affected by non-serious adverse events			
subjects affected / exposed	9 / 37 (24.32%)	5 / 32 (15.63%)	11 / 33 (33.33%)

Nervous system disorders Headache subjects affected / exposed occurrences (all)	4 / 37 (10.81%) 4	2 / 32 (6.25%) 2	5 / 33 (15.15%) 5
General disorders and administration site conditions Application site erythema subjects affected / exposed occurrences (all) Application site oedema subjects affected / exposed occurrences (all)	1 / 37 (2.70%) 1 1 / 37 (2.70%) 1	0 / 32 (0.00%) 0 0 / 32 (0.00%) 0	1 / 33 (3.03%) 1 0 / 33 (0.00%) 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