Clinical trial results:
Multicentre, prospective, double-blind, in parallel groups, randomized, placebo-controlled clinical trial to evaluate the short-term efficacy and safety of Betamethasone valerate 2.25 mg medicated plaster in patients with chronic lateral epicondylitis (tennis elbow)

Summary

EudraCT number	2014-004119-35
Trial protocol	IT
Global end of trial date	11 May 2016

Results information

Result version number	v1 (current)
This version publication date	01 January 2020
First version publication date	01 January 2020

Trial information

Trial identification

Sponsor protocol code	14I-BMT09

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	R&D Scientific Affairs Dept., IBSA Institut Biochimique SA, +41 583601000, sd@ibsa.ch
Scientific contact	R&D Scientific Affairs Dept., IBSA Institut Biochimique SA, +41 583601000, sd@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	12 December 2017
Is this the analysis of the primary completion data?	Yes
Primary completion date	11 May 2016
Global end of trial reached?	Yes
Global end of trial date	11 May 2016
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 significantly reduce pain in patients suffering from chronic lateral elbow tendinopathy, when topically applied daily, according to a 12 hours of application/day dose regimen, and during a period of 4 weeks.

Protection of trial subjects:

In case of insufficient pain relief, patients were allowed to take the rescue medication (paracetamol 500 mg).
If needed, cold applications (up to a maximum of three applications lasting 20 minutes each and performed at least 2 hours before any pain assessment), and braces for casting were allowed, and their use was to be recorded on the patient diary.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	31 March 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	Italy: 199
Worldwide total number of subjects	199
EEA total number of subjects	199

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)	185
From 65 to 84 years	14

85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Study Initiation Date: (First Patient First Visit)
31 March 2015
Study Completion Date: (Last Patient Last Visit)
11 May 2016

Pre-assignment

Screening details:

A total of 200 patients were screened and 199 were randomized to the assigned treatment

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, Assessor

Arms

Are arms mutually exclusive?	Yes
Arm title	BMV 2.25 mg medicated plaster

Arm description: -

Arm type	Experimental
Investigational medicinal product name	BMV 2.25 mg medicated plaster
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Medicated plaster
Routes of administration	Topical use

Dosage and administration details:

topically applied once a day on the most painful area of the affected body site, i.e. the lateral epicondyle

Arm title	Placebo

Arm description: -

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

Dosage and administration details:

topically applied once a day on the most painful area of the affected body site, i.e. the lateral epicondyle

Number of subjects in period 1	BMV 2.25 mg medicated plaster	Placebo
Started	101	98
Completed	93	90
Not completed	8	8
Consent withdrawn by subject	7	3
Adverse event, non-fatal	1	2
Lost to follow-up	-	2
Lack of efficacy	-	1

Baseline characteristics

Reporting groups	
Reporting group title	Overall Trial

Reporting group description: -

Reporting group values	Overall Trial	Total	
Number of subjects	199	199	
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)	185	185	
From 65-84 years	14	14	
85 years and over	0	0	
Gender categorical Units: Subjects			
Female	94	94	
Male	105	105	

End points

End points reporting groups

Reporting group title	BMV 2.25 mg medicated plaster
Reporting group description: -	
Reporting group title	Placebo
Reporting group description: -	

Primary: Pain Reduction

End point title	Pain Reduction
End point description:	
End point type	Primary
End point timeframe: Visit 5 (Day 28)	

End point values	BMV 2.25 mg medicated plaster	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	94	90		
Units: mm				
arithmetic mean (standard deviation)	-36.4 (± 27.0)	-25.7 (± 26.4)		

Statistical analyses

Statistical analysis title	Primary Endpoint
Comparison groups	BMV 2.25 mg medicated plaster v Placebo
Number of subjects included in analysis	184
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.028
Method	ANCOVA

Adverse events

Adverse events information

Timeframe for reporting adverse events:

The study period was divided into 5 visits: baseline (Visit 1), Visit 2 (Day 7) Visit 3 (Day 14) Visit 4 (Day 21) Visit 5 (Day 28). Adverse Events were evaluated at each visit.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	17.0

Reporting groups

Reporting group title	BMV 2.25 mg medicated plaster
Reporting group description: -	
Reporting group title	Placebo

Reporting group description: -

Serious adverse events	BMV 2.25 mg medicated plaster	Placebo	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 101 (0.00%)	0 / 98 (0.00%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events			

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

Non-serious adverse events	BMV 2.25 mg medicated plaster	Placebo	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	17 / 101 (16.83%)	16 / 98 (16.33%)	
Nervous system disorders			
Headache			
subjects affected / exposed	4 / 101 (3.96%)	7 / 98 (7.14%)	
occurrences (all)	4	8	
Dizziness			
subjects affected / exposed	0 / 101 (0.00%)	1 / 98 (1.02%)	
occurrences (all)	0	1	
Trigeminal neuralgia			
subjects affected / exposed	1 / 101 (0.99%)	0 / 98 (0.00%)	
occurrences (all)	2	0	
General disorders and administration			

site conditions			
Application site atrophy			
subjects affected / exposed	1 / 101 (0.99%)	2 / 98 (2.04%)	
occurrences (all)	1	2	
Application site erythema			
subjects affected / exposed	1 / 101 (0.99%)	1 / 98 (1.02%)	
occurrences (all)	1	1	
Application site irritation			
subjects affected / exposed	1 / 101 (0.99%)	1 / 98 (1.02%)	
occurrences (all)	1	1	
Application site pruritus			
subjects affected / exposed	0 / 101 (0.00%)	1 / 98 (1.02%)	
occurrences (all)	0	1	
Influenza like illness			
subjects affected / exposed	0 / 101 (0.00%)	1 / 98 (1.02%)	
occurrences (all)	0	1	

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