Clinical trial results:
COMBINED INTRA ARTICULAR CORTICOSTEROID AND EXERCISE IN PATIENTS WITH OSTEOARTHRITIS OF THE KNEE: A RANDOMISED TRIAL

Summary

EudraCT number	2012-002607-18
Trial protocol	DK
Global end of trial date	07 April 2014

Results information

Result version number	v1 (current)
This version publication date	01 January 2020
First version publication date	01 January 2020
Summary attachment (see zip file)	Publication (2012-002607-18) (2012-002607-18 (JAMA Int Med 2015).pdf)

Trial information

Trial identification

Sponsor protocol code	101.04

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01945749
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	The Parker Institute
Sponsor organisation address	Ndr. Fasanvej 57, Copenhagen, Denmark, 20000
Public contact	The Parker Institute, The Parker Institute, 0045 38164155, parker@frh.regionh.dk
Scientific contact	The Parker Institute, The Parker Institute, 0045 38164155, parker@frh.regionh.dk

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	07 July 2014
Is this the analysis of the primary completion data?	Yes
Primary completion date	07 April 2014
Global end of trial reached?	Yes
Global end of trial date	07 April 2014
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To investigate the effect of physiotherapeutic exercise in combination with pharmacological antiinflammatory treatment on patient reported pain in patients with knee osteoarthritis.

Protection of trial subjects:

Treated in routine care

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 October 2012
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	Denmark: 100
Worldwide total number of subjects	100
EEA total number of subjects	100

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)	59
From 65 to 84 years	41
85 years and over	0

Subject disposition

Recruitment
Recruitment details: -

Pre-assignment
Screening details: Screened 263

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

Arms	
Are arms mutually exclusive?	Yes
Arm title	Steroid
Arm description: Intra-articulr injectino of corticosteoid	
Arm type	Experimental
Investigational medicinal product name	Depo-medrol
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intraarticular use
Dosage and administration details: 40 mg milligram(s)	
Arm title	Placebo
Arm description: -	
Arm type	Placebo
Investigational medicinal product name	Natriumklorid isotonisk "SAD"
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intraarticular use
Dosage and administration details: 1 ml millilitre(s)	

Number of subjects in period 1	Steroid	Placebo
Started	50	50
Week2	50	50
Week14	47	46
week26	45	44

Completed	45	44
Not completed	5	6
Lack of time	3	1
Consent withdrawn by subject	1	1
Adverse event, non-fatal	1	3
Protocol deviation	-	1

Baseline characteristics

Reporting groups	
Reporting group title	Steroid
Reporting group description: Intra-articulr injectino of corticosteoid	
Reporting group title	Placebo
Reporting group description: -	

Reporting group values	Steroid	Placebo	Total
Number of subjects	50	50	100
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)	34	25	59
From 65-84 years	16	25	41
85 years and over	0	0	0
Gender categorical Units: Subjects			
Female	28	33	61
Male	22	17	39

Subject analysis sets	
Subject analysis set title	ITT
Subject analysis set type	Intention-to-treat
Subject analysis set description: ITT	

Reporting group values	ITT		
Number of subjects	100		
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)	59		
From 65-84 years	41		

85 years and over	0		

Gender categorical Units: Subjects			
Female Male			

End points

End points reporting groups	
Reporting group title	Steroid
Reporting group description: Intra-articulr injectino of corticosteoid	
Reporting group title	Placebo
Reporting group description: -	
Subject analysis set title	ITT
Subject analysis set type	Intention-to-treat
Subject analysis set description: ITT	

Primary: Change from baseline in knee pain	
End point title	Change from baseline in knee pain
End point description:	
End point type	Primary
End point timeframe: Week14	

End point values	Steroid	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	50	50		
Units: points				
least squares mean (standard error)	13.6 (± 1.8)	14.8 (± 1.8)		

Statistical analyses

Statistical analysis title	Statistical analysis
Comparison groups	Steroid v Placebo
Number of subjects included in analysis	100
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.05
Method	Mixed models analysis
Parameter estimate	Mean difference (net)
Point estimate	1.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.8
upper limit	6.2
Variability estimate	Standard error of the mean

Adverse events

Adverse events information	
Timeframe for reporting adverse events: Week14 Week26	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	1

Reporting groups	
Reporting group title	Steroid
Reporting group description: -	
Reporting group title	Placebo
Reporting group description: -	

Serious adverse events	Steroid	Placebo	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	

Frequency threshold for reporting non-serious adverse events: 2 %

Non-serious adverse events	Steroid	Placebo	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	1 / 50 (2.00%)	2 / 50 (4.00%)	
Injury, poisoning and procedural complications			
Pain in extremity	Additional description: Increased pain following injection		
subjects affected / exposed	1 / 50 (2.00%)	2 / 50 (4.00%)	
occurrences (all)	1	2	

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