



Clinical trial results:

An open label study of intra-articular steroid injection in the management of symptomatic knee OA

Summary

EudraCT number	2009-015849-22
Trial protocol	GB
Global end of trial date	11 December 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)	TASK Summary (TASK Paper1.2015.04.23.published.pdf)

Trial information

Trial identification

Sponsor protocol code	2009/147
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Additional study identifiers

ISRCTN number	ISRCTN07329370
ClinicalTrials.gov id (NCT number)	-
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Salford Royal NHS Foundation Trust
Sponsor organisation address	Stott Lane , Salford, United Kingdom, M6 8HD
Public contact	Professor Terence O'Neill, University of Manchester, +44 1612064627, Terence.o'Neill@srft.nhs.uk
Scientific contact	Professor Terence O'Neill, University of Manchester, +44 1612064627, Terence.o'Neill@srft.nhs.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	Final
Date of interim/final analysis	26 June 2015
Is this the analysis of the primary completion data?	Yes
Primary completion date	11 December 2014
Global end of trial reached?	Yes
Global end of trial date	11 December 2014
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To determine i) whether clinical response to intra-articular steroids in knee OA correlates with a decrease in size and a decrease in perfusion of the synovium. and ii) whether relapse of symptoms after intra-articular steroids is associated with recurrence of synovitis.

Protection of trial subjects:

Treatment given within clinical trial setting as part of routine clinical care. All adverse events reported descriptively and reviewed by CI & Sponsor.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	11 May 2010
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	United Kingdom: 120
Worldwide total number of subjects	120
EEA total number of subjects	120

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)	120
From 65 to 84 years	0

85 years and over	0
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Subject disposition

Recruitment

Recruitment details:

Recruitment details:

Participants meeting eligibility criteria were recruited from a single site in England between 11/05/2010 to 15/12/2014.

Pre-assignment

Screening details:

Patients screened for eligibility by the research team and were referred from a patient identifiable centre

Period 1

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

Blinding implementation details:

Not applicable

Arms

Arm title	overall trial
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Arm description:

Standard care

Arm type	standard care
Investigational medicinal product name	Depomedrone
Investigational medicinal product code	402AB04
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intraarticular use

Dosage and administration details:

80mg

Number of subjects in period 1	overall trial
Started	120
Completed	120

Baseline characteristics

Reporting groups

Reporting group title	overall trial
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Reporting group description: -

Reporting group values	overall trial	Total	
Number of subjects	120	120	
Age categorical			
Adults between 40 to 79			
Units: Subjects			
Adults (18-64 years)	120	120	
Gender categorical			
Units: Subjects			
Female	74	74	
Male	46	46	

End points

End points reporting groups

Reporting group title	overall trial
Reporting group description:	
Standard care	
Subject analysis set title	overall trial
Subject analysis set type	Full analysis
Subject analysis set description:	
overall trial analysis	

Primary: Pain Score

End point title	Pain Score
End point description:	
End point type	Primary
End point timeframe:	
From Baseline to final follow-up	

End point values	overall trial	overall trial		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	120	120		
Units: VAS				
arithmetic mean (standard deviation)				
VAS	3.30 (± 2.7)	3.30 (± 2.7)		

Attachments (see zip file)	Table 2/Table 2.docx
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Statistical analyses

Statistical analysis title	overall trial
Statistical analysis description:	
see publication	
Comparison groups	overall trial v overall trial
Number of subjects included in analysis	240
Analysis specification	Pre-specified
Analysis type	equivalence ^[1]
P-value	= 0.001
Method	Stata
Parameter estimate	Odds ratio (OR)
Point estimate	3.3

Confidence interval	
level	95 %
sides	2-sided
lower limit	2.7
upper limit	3.8
Variability estimate	Standard deviation
Dispersion value	3.3

Notes:

[1] - see publication

Adverse events

Adverse events information

Timeframe for reporting adverse events:

All AEs and SAE's shall be recorded from the time a participant consents to join the study until the last study visit.

Assessment type	Non-systematic
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Dictionary used

Dictionary name	no dictionary
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Dictionary version	0
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Reporting groups

Reporting group title	Treatment Arm
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Reporting group description:

They had a contrastenhanced (CE) MRI immediately prior to an intraarticularsteroid injection with a repeat scan within20 days.

Serious adverse events	Treatment Arm		
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 120 (1.67%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Infections and infestations			
Infection			
subjects affected / exposed	2 / 120 (1.67%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		

Frequency threshold for reporting non-serious adverse events: 5 %

Non-serious adverse events	Treatment Arm		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	50 / 120 (41.67%)		
General disorders and administration site conditions			
pain			
subjects affected / exposed	50 / 120 (41.67%)		
occurrences (all)	50		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
04 February 2010	This extended the study to include patients who had had either an MRI, Arthroscopy or X ray in the previous 24 months
22 July 2010	Removal of upper age limit; Reduction of wash out period; Alternative recruitment strategies; Use of telephone screening questionnaire for patients who contact via advertising
28 January 2011	Addition of recruitment letters and a questionnaire to facilitate a more effective recruitment strategy through GP practices; Change to inclusion criteria; change to time between screening, baseline and week one appointments; use of ultrasound has been added to the protocol...
22 September 2011	Addition of Sub Study – KOPS
12 April 2012	To allow the recruitment of additional 80 participants for collection of new baseline information on other predictors to intra-articular steroid injection in knee OA (CLIPs sub-study). The study already has sufficient data on structural changes assessed by magnetic resonance imaging (MRI) scan. Therefore, the extension of the study will involve removal of MRI and hence blood test (eGFR) will not be needed for screening of renal function.
27 February 2013	To allow telephone review call window of 28 +/- 14 (i.e. between 14 days and 42 days), instead of every 2 weeks to accommodate times when research nurse or participants may be unavailable for the reviews. The PIS will also include additional clause inviting participants to contact the research team if their pain changes. Some of the other changes are for clarity and also for administrative reasons rather than changes to the actual conduct of the study.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

None

Notes:

Online references

<http://www.ncbi.nlm.nih.gov/pubmed/26116548>