



Clinical trial results:

The Efficacy of Continuous Intra-articular Infusion of Local Anaesthetic Agent following Elective Primary Hip Arthroplasty

Summary

EudraCT number	2011-001510-33
Trial protocol	GB
Global end of trial date	26 August 2015

Results information

Result version number	v1 (current)
This version publication date	17 December 2020
First version publication date	17 December 2020

Trial information

Trial identification

Sponsor protocol code	RR11/9781
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Additional study identifiers

ISRCTN number	ISRCTN24271997
ClinicalTrials.gov id (NCT number)	-
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Leeds Teaching Hospitals NHS Trust
Sponsor organisation address	Beckett Street , Leeds, United Kingdom, LS9 7TF
Public contact	Dr Martin Stone , Leeds Teaching Hospitals NHS Trust , martin.stone@nhs.net
Scientific contact	Dr Martin Stone , Leeds Teaching Hospitals NHS Trust , martin.stone@nhs.net

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 August 2015
Is this the analysis of the primary completion data?	Yes
Primary completion date	26 August 2015
Global end of trial reached?	Yes
Global end of trial date	26 August 2015
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

To determine whether the use of a continuous intra-articular infusion of local anaesthetic might reduce the need for post-operative opiate use in patients undergoing hip replacement.

Protection of trial subjects:

This clinical trial, which involves the use of an investigational medicinal product has been designed and will be run in accordance with the Principles of GCP and the current regulatory requirements, as detailed in the Medicines for Human Use (Clinical Trials) Regulations 2004 (UK S.I. 2004 / 1031) and any subsequent amendments of the clinical trial regulations.

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**

Country: Number of subjects enrolled	United Kingdom: 99999
Worldwide total number of subjects	99999
EEA total number of subjects	99999

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)	99999
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Patients attending for unilateral, elective primary hip arthroplasty will be randomised into one of two groups, Treatment, and Control. A verbal explanation of the trial and Patient Information Leaflet (PIL) will be provided by the authorised trial clinician for the patient to consider.

Pre-assignment

Screening details:

It is essential that patients greater than 70 years old are recruited to the study. Many patients presenting for primary hip arthroplasty are in this age group and it is anticipated that reduced post operative morphine consumption in these patients will be of particular benefit.

Period 1

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

Blinding implementation details:

The ODP will complete a tick-box form on carbon paper which records the contents of the pain pump and the medicinal product batch numbers. The top copy will bear a patient information sticker and the other copy will have only the study reference number and no patient identifiable information. The top copy of the form is placed in a sealed, opaque envelope which is stapled to the inside of the patient's notes. The other copy is placed in a sealed, opaque envelope and put into a secure storage

Arms

Are arms mutually exclusive?	Yes
Arm title	Treatment

Arm description:

Patients in this group will receive a one-off bolus of local anaesthetic mixture followed by an infusion of bupivacaine local anaesthetic over the following 48 hours.

Arm type	Experimental
Investigational medicinal product name	bupivacaine local anaesthetic
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection/infusion
Routes of administration	Intravenous use

Dosage and administration details:

Bupivacaine hydrochloride is presented as a clear, colourless solution for injection in a range of concentrations. The 2.5mg/ml concentration is used in the LIA study. Patients in this group will receive a one-off bolus of local anaesthetic mixture followed by an infusion of bupivacaine local anaesthetic over the following 48 h.

Arm title	Placebo
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Arm description:

Patients in this group will receive a one-off bolus of local anaesthetic mixture followed by an infusion of saline placebo over the following 48 h.

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection/infusion
Routes of administration	Intravenous use

Dosage and administration details:

Patients in this group will receive a one-off bolus of local anaesthetic mixture followed by an infusion of saline placebo over the following 48 h.

Number of subjects in period 1	Treatment	Placebo
Started	99998	1
Completed	99998	1

Baseline characteristics

Reporting groups

Reporting group title	Main Trial Period
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Reporting group description: -

Reporting group values	Main Trial Period	Total	
Number of subjects	99999	99999	
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)	99999	99999	
From 65-84 years	0	0	
85 years and over	0	0	
Gender categorical			
Units: Subjects			
Female	0	0	
Male	99999	99999	

End points

End points reporting groups

Reporting group title	Treatment
Reporting group description: Patients in this group will receive a one-off bolus of local anaesthetic mixture followed by an infusion of bupivacaine local anaesthetic over the following 48 hours.	
Reporting group title	Placebo
Reporting group description: Patients in this group will receive a one-off bolus of local anaesthetic mixture followed by an infusion of saline placebo over the following 48 h.	

Primary: 30% reduction in the amount of opiate analgesia required by patients 48 hour post-operative period

End point title	30% reduction in the amount of opiate analgesia required by patients 48 hour post-operative period ^[1]
End point description: A full data set to satisfy the requirements for the EudraCT upload is unavailable as the data analysis is incomplete for this trial. Following discussion with the UK regulator the MHRA its was agreed that the trial teams would not pursue publication for this trial and results analysis was halted. It was agreed with the MHRA in September 2019 that a full data upload on EudraCT is not required.	
End point type	Primary
End point timeframe: The primary endpoint is a 30% reduction in the amount of opiate analgesia required by patients in the 48 hour post-operative period in the treatment group compared to the placebo group.	

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: A full data set to satisfy the requirements for the EudraCT upload is unavailable as the data analysis is incomplete for this trial. Following discussion with the UK regulator the MHRA its was agreed that the trial teams would not pursue publication for this trial and results analysis was halted. It was agreed with the MHRA in September 2019 that a full data upload on EudraCT is not required.

End point values	Treatment	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0 ^[2]	0 ^[3]		
Units: participants				

Notes:

[2] - data analysis is incomplete for this trial.

[3] - data analysis is incomplete for this trial.

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information^[1]

Timeframe for reporting adverse events:

AEs will be collected for all patients and will be evaluated for duration and intensity according to the NCRI Common Toxicity Criteria.

Adverse event reporting additional description:

AEs will be collected for all patients from first dose of protocol treatment until 30 days after the last dose of treatment with a protocol IMP.

Information about AEs, whether volunteered by the patient, discovered by the investigator questioning or detected through physical examination, laboratory test or other investigation will be collected

Assessment type	Systematic
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Dictionary used

Dictionary name	CTCAE
Dictionary version	4.0

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

Notes:

[1] - There are no non-serious adverse events recorded for these results. It is expected that there will be at least one non-serious adverse event reported.

Justification: A full data set to satisfy the requirements for the EudraCT upload is unavailable as the data analysis is incomplete for this trial. Following discussion with the UK regulator the MHRA it was agreed that the trial teams would not pursue publication for this trial and results analysis was halted. It was agreed with the MHRA in September 2019 that a full data upload on EudraCT is not required.

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
26 August 2015	The trial had multiple substantial amendments, but a full data set to satisfy the requirements for the EudraCT upload is unavailable as the data analysis is incomplete for this trial. Following discussion with the UK regulator the MHRA it was agreed that the trial teams would not pursue publication for this trial and results analysis was halted. It was agreed with the MHRA in September 2019 that a full data upload on EudraCT is not required.

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.

A full data set to satisfy the requirements for the EudraCT upload is unavailable as the data analysis is incomplete for this trial. Following discussion with the UK regulator the MHRA it was agreed that the trial teams would not pursue publication

Notes: