Clinical trial results:
Feasibility, efficacy and acceptability of injected buprenorphine as treatment for opiate users who persist in injecting illicit heroin through opiate maintenance treatment

Summary

EudraCT number	2011-001088-28
Trial protocol	GB
Global end of trial date	10 January 2020

Results information

Result version number	v1 (current)
This version publication date	23 April 2020
First version publication date	23 April 2020
Summary attachment (see zip file)	Cancelled Before Active Statement (Cancelled before activity statement.pdf)

Trial information

Trial identification

Sponsor protocol code	BRIO

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	South London and Maudsley NHS Foundation Trust
Sponsor organisation address	Denmark Hill, London, United Kingdom, SE5 8AZ
Public contact	Professor John Strang, South London and Maudsley NHS Foundation Trust, 0044 02078480819, john.strang@kcl.ac.uk
Scientific contact	Professor John Strang, South London and Maudsley NHS Foundation Trust, 0044 02078480819, john.strang@kcl.ac.uk
Sponsor organisation name	King's College London
Sponsor organisation address	The Strand, London, United Kingdom, WC2R 2LS
Public contact	Professor John Strang, King's College London, 44 02078480819, john.strang@kcl.ac.uk
Scientific contact	Professor John Strang, King's College London, 44 02078480819, john.strang@kcl.ac.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	10 January 2020
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	10 January 2020
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

The trial aims to examine the safety, acceptability, and physiological responses to high dose injectable buprenorphine, for subjects not responding to their current maintenance treatment. The key outcomes are as follows:
- Feasibility, of recruiting and maintaining subjects with a daily injection (IV/IM) of buprenorphine (successful retention outcome defined as 60+ %)
- Reduction or cessation of injecting street heroin (successful outcome defined as 50% of urine tests negative for illicit heroin (i.e. morphine) in weeks 14-26)
- Safety (of daily IV/IM injection of buprenorphine (assessed by observations of IMP administration, laboratory testing, cardio respiratory monitoring, and adverse events)

Protection of trial subjects:

N/A

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	10 January 2020
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:

99999 is "Not applicable" value or 0 participants, this trial was discontinued with no participants enrolled in the trial

Pre-assignment

Screening details:

N/A

Period 1

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

Blinding implementation details:

N/A open label

Arms

Arm title	Injectable Buprenorphine

Arm description:

Subjects will be inducted onto injectable buprenorphine according to the following regime:

- Week 1- buprenorphine ampoules 3mg per day
- Week 2- buprenorphine ampoules 6mg per day
- Week 4- buprenorphine ampoules 9mg per day

Arm type	Experimental
Investigational medicinal product name	Temgesic
Investigational medicinal product code	
Other name	Buprenorphine
Pharmaceutical forms	Injection
Routes of administration	Intramuscular and intravenous use

Dosage and administration details:

9 mg milligram(s) per day

Investigational medicinal product name	Suboxone
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Sublingual tablet
Routes of administration	Sublingual use

Dosage and administration details:

24 mg milligram(s) per day

Number of subjects in period 1	Injectable Buprenorphine
Started	99999
Completed	99999

Baseline characteristics

Reporting groups	
Reporting group title	Whole trial period

Reporting group description: -

Reporting group values	Whole 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	99999	99999	
Male	0	0	

End points

End points reporting groups

Reporting group title	Injectable Buprenorphine

Reporting group description:

Subjects will be inducted onto injectable buprenorphine according to the following regime:

- Week 1- buprenorphine ampoules 3mg per day
- Week 2- buprenorphine ampoules 6mg per day
- Week 4- buprenorphine ampoules 9mg per day

Primary: feasibility, of recruiting and maintaining (successful retention outcome defined as 60+%) subjects with a daily injection (IV/IM) of buprenorphine

End point title	feasibility, of recruiting and maintaining (successful retention outcome defined as 60+%) subjects with a daily injection (IV/IM) of buprenorphine[1]

End point description:

99999 is "Not applicable" value or 0 participants, this trial was discontinued with no participants enrolled in the trial.

End point type	Primary

End point timeframe:

N/A

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: No statistical analyses have been specified for this primary end point

End point values	Injectable Buprenorphine			
Subject group type	Reporting group			
Number of subjects analysed	99999[2]			
Units: Number of subjects recruited	99999			

Notes:

[2] - N/A

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]	
Timeframe for reporting adverse events: N/A	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	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: No subjects were enrolled in the trial hence results are not available

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

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

No subjects were enrolled in the trial hence results are not available

Notes: