



Clinical trial results:

A randomised double blind placebo controlled pilot trial of oxytocin efficacy in treating detoxified opioid dependent individuals

Summary

EudraCT number	2014-002708-26
Trial protocol	GB
Global end of trial date	06 October 2017

Results information

Result version number	v1 (current)
This version publication date	07 March 2019
First version publication date	07 March 2019

Trial information

Trial identification

Sponsor protocol code	CRC341
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Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	University of surrey
Sponsor organisation address	Stag Hill Campus, Guildford, United Kingdom, GU2 7XH
Public contact	RIGO, University of Surrey, +44 01483 689783, RIGO@surrey.ac.uk
Scientific contact	RIGO, University of Surrey, +44 01483 689783, RIGO@surrey.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	05 February 2019
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	06 October 2017
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

The primary objective will be to investigate the efficacy of oxytocin (Syntocinon) in retaining post-detoxification opioid (e.g. heroin) dependent individuals in inpatient rehabilitation programme and in preventing relapse to opioids (e.g. heroin) or other drug use.

Protection of trial subjects:

No participants completed the protocol of this study, the study was terminated due to IMP going out of date and no funds for new IMP

Background therapy:

n/a

Evidence for comparator:

n/a

Actual start date of recruitment	06 April 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	United Kingdom: 3
Worldwide total number of subjects	3
EEA total number of subjects	3

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)	3
From 65 to 84 years	0

85 years and over	0
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Subject disposition

Recruitment

Recruitment details:

Only one participant was recruited and dosed, they left the trial before they could complete. Recruitment was difficult due to the nature of the participants condition, and overly burdensome protocol and strict exclusion criteria.

Pre-assignment

Screening details:

n/a

Period 1

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

Blinding implementation details:

Blinding was carried out by a statistician, sealed in envelopes and stored with the unblinded monitor.

Arms

Are arms mutually exclusive?	Yes
Arm title	placebo arm

Arm description:

Placebo

Arm type	Placebo
Investigational medicinal product name	placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray
Routes of administration	Nasal use

Dosage and administration details:

No active substance one spray into the nasal cavity

Arm title	IMP Arm
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Arm description:

Subjects allocated into IMP arm

Arm type	Experimental
Investigational medicinal product name	Syntocin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal drops, suspension
Routes of administration	Nasal use

Dosage and administration details:

5UI sprayed directly into the nasal cavity

Number of subjects in period 1	placebo arm	IMP Arm
Started	1	2
Completed	1	2

Baseline characteristics

End points

End points reporting groups

Reporting group title	placebo arm
Reporting group description: Placebo	
Reporting group title	IMP Arm
Reporting group description: Subjects allocated into IMP arm	

Primary: reduction in lapsing into opioid dependency

End point title	reduction in lapsing into opioid dependency ^[1]
End point description: it was hoped participants would not return to opioid dependency	
End point type	Primary
End point timeframe: ongoing	

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 Participants completed the trial. No statistical analysis was possible.

End point values	placebo arm	IMP Arm		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1 ^[2]	2 ^[3]		
Units: 1	0	0		

Notes:

[2] - no participants completed the protocol

[3] - No Participants completed the protocol

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information^[1]

Timeframe for reporting adverse events:

6 months

Adverse event reporting additional description:

n/a no subjects passed the whole protocol. No SAEs

Assessment type	Non-systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	21
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Frequency threshold for reporting non-serious adverse events: 1 %

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: There was no adverse events as we had no participants last more than one day in the trial.

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
01 March 2015	Change of IMP supplier
01 November 2015	New IMP Supplier
01 September 2016	Removal of saliva cortisol measurement
01 May 2017	Change in inclusion criteria, participant added who are currently taking antidepressants - previously excluded.

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.

No Participant completed the trial so no data was attained

Notes: