

Randomised double-blind placebo-controlled trial of nasal oxytocin spray in mothers of preterm infants

Submission date
12/09/2003

Recruitment status
No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date
12/09/2003

Overall study status
Completed

☐ Statistical analysis plan

☒ Results

Last Edited
20/02/2008

Condition category
Pregnancy and Childbirth

☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N0263115170

Study information

Scientific Title

Study objectives

Does oxytocin nasal spray enable mothers of preterm infants to express more breast milk more easily?

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Not Specified

Participant information sheet

Health condition(s) or problem(s) studied

Pregnancy and Childbirth: Breast feeding

Interventions

- A. Oxytocin nasal spray
- B. Placebo

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

oxytocin

Primary outcome measure

Total volume of expressed breast milk, proportion of mothers breast feeding their infant.

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/08/2002

Completion date

01/08/2006

Eligibility

Key inclusion criteria

60 Patients from Obstetrics

Participant type(s)

Patient

Age group

Adult

Sex

Female

Target number of participants

60

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

01/08/2002

Date of final enrolment

01/08/2006

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

MRC Childhood Nutrition Research Centre

London

United Kingdom
WC1N 1EH

Sponsor information

Organisation

Department of Health (UK)

Sponsor details

Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type

Government

Website

<http://www.doh.gov.uk>

Funder(s)

Funder type

Government

Funder Name

University College London Hospitals NHS Trust

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/05/2006		Yes	No