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Intranasal oxytocin for treating mother-infant attachment problems in postnatal depression

Submission date
11/11/2011

Recruitment status
No longer recruiting

Registration date
08/03/2012

Overall study status
Completed

Last Edited
22/08/2016

Condition category
Pregnancy and Childbirth

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
We are looking at whether oxytocin, a naturally occurring chemical in our bodies, helps mums and their babies to bond.

It is generally accepted that a strong bond between a mum and her baby is important. Both for the present and future wellbeing of the baby, but also for mums physical and mental health. Unfortunately, the strength of that bond is sometimes threatened. Family stress, illnesses and mental health problems can all make it harder for a mother and baby to bond.

We know from existing research that there is a hormone, oxytocin, which is important in human relationships. Our question is, in mother-baby relationships which are affected by a mental illness such as depression, can oxytocin help improve that relationship?

Who can participate?
Mums aged 18-50, who have recently had a new baby, and have been experiencing difficulties with low mood. Please note that mums who are pregnant again cannot take part in our study.

What does the study involve?
We hope to answer our research question by asking participants to spend some time playing with their baby, after they (the mums) have been given a nasal spray containing a man-made copy of oxytocin. If you agree to take part, we will film a short video of you and your baby and study your behaviour. We will compare this with a video of when you have been given a spray containing only saline (salty water), and see if there are any differences.

To do this, a member of the study team will visit you at home on two occasions, filming a five-minute video each time. On one visit you will be given oxytocin spray, on the other occasion, you will be given the saline spray. Neither you nor the researcher watching the video will know which spray is which. We will also ask you to complete short questionnaires about your mood and your feelings towards your baby. Each visit will last no longer than one and a half hours. We will reimburse you £20 to recognise the trouble you have taken to help us.

As oxytocin is a naturally occurring hormone, most people do not experience side effects. The study team will speak to you in more detail, but you should know that the common ones (affecting 1 in 100 to 1 in 10 people) are headache, a fast or slow heart rate, and feeling sick or vomiting.

If you do experience a side-effect, the team will inform the sponsor and the Ethics Committee who have reviewed the study, who will then decide whether the study should continue. We will also, with your permission, inform your GP, so that they can arrange to see you if they feel it is necessary.

What are the possible benefits and risks of participating?
It is hoped that by taking part in this research, you will be providing valuable information about how mums with postnatal depression might be helped to bond with their babies.

Where is the study run from?
The University of Glasgow.

When is the study starting and how long is it expected to run for?
We hope to run the study between January and May 2012.

Who is funding the study?
The University of Glasgow.

Who is the main contact?
Dr Helen Minnis
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Contact information

Type(s)
Scientific

Contact name
Dr Helen Minnis

Contact details
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Additional identifiers

Protocol serial number
Version 1

Study information

Scientific Title
Crossover trial of intranasal oxytocin for treating mother-infant attachment problems in postnatal depression

Study objectives
The importance of a secure bond between mother and baby is well-understood. Its disruption has consequences for the mental and physical well-being of both. Negative influences such as an adverse environment, maternal mental health problems and a mothers own difficult childhood may put the normal mother-infant bond at risk. For example, postnatal depression is thought to affect at least one in ten mothers in the months following the birth of their baby. Affected mothers may not be able to bond as well with their baby, with serious adverse consequences for both mother and infant. The baby's cognitive development may be impaired, and mother-infant attachment compromised. Infants of depressed mothers have been shown to be less responsive to social cues and it is suggested that this may make them less able to empathise with others in later life.

Work from animal studies suggests that the hormone oxytocin is important in helping mothers and babies to bond. Oxytocin has been shown to increase the amount of time people spend focusing on the eye region of anothers face. It also has actions within the body, and is used by obstetricians to induce labour. In the study of human relationships, oxytocin is often administered artificially, most usually by nasal spray, to investigate its effects on behaviour.

We hypothesise that, as bonding behaviours such as eye contact are observed to be reduced in mothers with depression, oxytocin administration might have a positive effect. Oxytocin has not been investigated for this indication before. To test our hypothesis, we plan to observe mother-baby interaction following administration of short-acting oxytocin to the mother. This will be given by nasal spray, in the standard dose used in previous human studies. The nasal route is thought to be the most direct way of getting oxytocin to the brain, with minimal side-effects on the rest of the body. We will also ask the mother to complete a questionnaire about her feelings towards her baby. The same will be done following administration of placebo and results from the two trials compared. If we find that oxytocin does have a positive effect on duration of eye contact, then this study may serve to inform future studies which could fully evaluate whether oxytocin might have therapeutic potential in mother-infant relationships affected by postnatal depression.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Crossover trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied

Postnatal mental health / mother-infant attachment

Interventions
Intranasal administration of 24IU Syntocinon® (oxytocin) versus Intranasal administration of placebo (0.9% sodium chloride solution)

Video will be recorded of the mother-infant interaction following intranasal administration of Syntocinon® and placebo. The videos will be compared to see if there are any differences.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Duration of mutual eye region gaze between mother and baby

Key secondary outcome(s))
1. CARE index will be calculated from the video footage (ie. at 45mins post-spray administration on both occasions)
2. Neonatal perception index will be completed at 0 and 45 minutes each time

Completion date
31/05/2012

Eligibility

Key inclusion criteria
1. Mother with history of low mood (recorded Edinburgh Postnatal Depression Score of ten or greater) with baby aged 8-16 weeks
2. Mother aged 18 50 years

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Female

Key exclusion criteria

1. Baby born before 38 weeks
2. Significant obstetric complications
3. Significant medical condition of mother or baby
4. Substantial neurological or visual impairment of mother or baby
5. Mother non-English speaking
6. Mother continuing to breast feed
7. Mother has physical condition which might affect nasal drug absorption (eg. URTI)
8. Mother responsible for care of another child at time of home visit
9. Mother pregnant
10. Mothers on antidepressant medication will not be excluded from the study; however we will record if a subject is on medication

Date of first enrolment
01/12/2011

Date of final enrolment
31/05/2012

Locations

Countries of recruitment
United Kingdom

Scotland

Study participating centre
University of Glasgow
Glasgow
United Kingdom
G3 8SJ

Sponsor information

Organisation
NHS Greater Glasgow & Clyde (UK)

ROR
https://ror.org/05kdz4d87

Funder(s)

Funder type
University/education

Funder Name
University of Glasgow (UK) ref: GN11KH391

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Results and Publications

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?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes