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Reducing Excess Salivation in clozapine Treatment: hyoscine for the treatment of clozapine induced nocturnal sialorrhoea

Submission date	Recruitment status	[_] Prospectively registered
11/12/2009	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
16/03/2010	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
06/10/2020	Digestive System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
1.0

Study information

Scientific Title
Pilot double blind randomised placebo controlled crossover trial of hyoscine hydrobromide for the treatment of clozapine-induced nocturnal sialorrhoea

Acronym
REST

Study objectives
This is a pilot study to obtain data on the efficacy of hyoscine hydrobromide 0.3 mg nocte in reducing nocturnal sialorrhoea in patients treated with clozapine.

Ethics approval required
Old ethics approval format

Ethics approval(s)
South East Research Ethics Committee (REC) approved on the 22nd October 2009 (ref: 09/H1102 /103)

Study design
Single centre double blind randomised placebo controlled crossover trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Nocturnal sialorrhoea

Interventions
1. Oral hyoscine hydrobromide 0.3 mg nocte for the treatment of nocturnal sialorrhoea in patients taking clozapine
2. Matching placebo

The trial will consist of 2 washout periods of 1 week and two treatment phases of 4 weeks, totalling 10 weeks per participant.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Hyoscine hydrobromide, clozapine

Primary outcome measure
Score on the Toronto Nocturnal Hypersalivation Scale (TNHS), collected daily

Secondary outcome measures
1. Overnight increase in mass of pillowcase, collected daily
2. Change in diameter of wet area on pillowcase, collected daily
3. Score on EQ-5D, collected daily

Overall study start date
02/01/2010

Completion date
31/03/2010

Eligibility

Key inclusion criteria
1. Diagnosis of schizophrenia or schizoaffective disorder as per Diagnostic and Statistical Manual, Fourth Edition, Text Revision (DSM IV-TR) criteria
2. Receiving clozapine for at least two weeks
3. Clozapine dose in the range 200 - 900 mg per day
4. Able to speak English
5. Have a minimum score of 2 on the Toronto Nocturnal Hypersalivation Scale (TNHS) on 4 occasions, in the 28 days prior to randomisation in the trial
6. Aged between 18 and 65 years of age, either sex
7. Capable of understanding the information given and giving fully informed consent prior to any study specific procedures

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex

Both

Target number of participants
12

Total final enrolment
14

Key exclusion criteria
1. Medical conditions that could influence hypersalivation (e.g. idiopathic Parkinsons Disease)
2. History of an allergic reaction to hyoscine hydrobromide
3. Any of the following contra-indications to hyoscine as stated in the British National Formulary and electronic Medicines Compendium:
3.1. Prostatic enlargement
3.2. Myasthenia gravis
3.3. Pyloric stenosis
3.4. Paralytic ileus
3.5. Hypertension
3.6. Pregnancy
3.7. Tachycardia
4. A woman of childbearing potential, who has tested negative for pregnancy, unable or unwilling to use appropriate contraception during the study
5. Participation in another therapeutic study within the preceding 12 weeks or use of other investigational drugs or agents
6. Lack of capacity to provide informed consent to the proposed intervention

Date of first enrolment
02/01/2010

Date of final enrolment
31/03/2010

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Senior Lecturer
London
United Kingdom
SE5 8AF

Sponsor information

Organisation
Kings College London - Joint Clinical Trials Office (UK)

Sponsor details
3rd floor, Conybeare House
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Sponsor type
University/education

Website
http://jcto.co.uk

ROR
https://ror.org/0220mzb33

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research (NIHR) (UK) - Biomedical Research Centre for Mental Health award, administered by the Institute of Psychiatry at Kings College London

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	01/03/2019	06/10/2020	Yes	No
HRA research summary			28/06/2023	No	No