

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

Submission date 11/12/2009	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 16/03/2010	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 06/10/2020	Condition category Digestive System	<input type="checkbox"/> 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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Additional identifiers

Protocol serial number

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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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

United Kingdom

England

Study participating centre

Senior Lecturer

London

United Kingdom

SE5 8AF

Sponsor information

Organisation

Kings College London - Joint Clinical Trials Office (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

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