Antipsychotics: about Safety, Acceptation and Pharmacokinetics in adults

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In the ASAP study, we aim to investigate pain associated with capillary sampling in a population of patients with serious psychiatric problems, compared to pain associated with standard venous access. This study is a pilot for a planned larger study…

Ethical review	Approved WMO
Status	Completed
Health condition type	Schizophrenia and other psychotic disorders
Study type	Observational invasive

Summary

ID

NL-OMON53723

Source
ToetsingOnline

Brief title
ASAP

Condition

- Schizophrenia and other psychotic disorders

Synonym
psychoses, psychotic disorder

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Adults, Antipsychotic, Pain, Safety

Outcome measures

Primary outcome

The main study parameter is pain measured by the VAS scale.

Secondary outcome

The percentage of participants able to perform the procedure themselves. Scores

about the acceptability given by the participants. The sampling and work flow

of the finger pick.

Study description

Background summary

Antipsychotics are the mainstay of treatment for schizophrenia and are an important adjunctive treatment for bipolar disorders. However, using antipsychotics contributes to higher mortality risk in the population and some antipsychotics need therapeutic drug monitoring. Therefore monitoring blood parameters is indicated. The metabolic parameters and blood levels of clozapine needs to be tested frequently. In clinical practice it has proven to be challenging. One burden in monitoring is performing a phlebotomy. Another option could be performing a capillary sampling.

Study objective

In the ASAP study, we aim to investigate pain associated with capillary sampling in a population of patients with serious psychiatric problems, compared to pain associated with standard venous access. This study is a pilot for a planned larger study.

Study design

An open, single group, non-blinded within subject design.

Study burden and risks

The participants will be asked to perform one extra capillary blood and fill in the questionnaires. This consist of one visit. Performing a capillary blood collection comes with a possibility of a short time skin irritation. Further, there are no risks associated with the participation. no influence on therapy
The participants are selected of a population of patient

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

- Age >= 18 years
- Written informed consent has been obtained from the patient
- Using an antipsychotic
- Scheduled for metabolic screening according to standard clinical care

Exclusion criteria

- Unable to draw samples for study purposes
- Language barriers
- Unable to give informed consent to all aspects of the study

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	28-07-2023
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO Date:	30-06-2023
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	11-06-2024
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL82911.078.22