Capillary Olanzapine Sampling Method validatiOn Study

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Clinical validation of capillary microsampling with finger pricks for olanzapine. The validation method is performed in accordance with the EM guideline. In this process, the analytical methods are assessed for selectivity, carry-over, lower limit...

Ethical review	Approved WMO
Status	Pending
Health condition type	Psychiatric disorders NEC
Study type	Observational invasive

Summary

ID

NL-OMON56914

Source
ToetsingOnline

Brief title
COSMOS

Condition

- Psychiatric disorders NEC

Synonym
Concentration of olanzapine in blood

Research involving
Human

Sponsors and support

Primary sponsor: Maasstadziekenhuis
Source(s) of monetary or material Support: Onderzoeksgelden MaasstadLab

Intervention

Keyword: Capillary sampling, Olanzapine, Validation, Venepuncture

Outcome measures

Primary outcome

Comparison of capillary microsampling to venepunctures to clinically validate capillary microsampling of olanzapine.

Secondary outcome

To obtain patient*s perspectives on the finger prick capillary microsampling compared to the standard method by venepuncture.

Study description

Background summary

To ensure adequate exposure to drugs, blood concentration measurements can be used to optimize drug doses, a practice known as therapeutic drug monitoring (TDM). Applying TDM for antipsychotic drug users is important to gain insight into the relationship between drug concentration, efficacy, and toxicity. Venous blood sampling is currently the standard method used for TDM. However, this method is quite invasive and can cause psychological distress in patients with pre-existing fear of injections. To reduce the patient's burden, other methods such as capillary microsampling have been designed, in which a finger prick is sufficient for blood collection. This is way less invasive than venipuncture and enables patients to perform one or more finger pricks themselves. Furthermore, capillary microsampling offers the possibility to collect blood at home, resulting in fewer hospital visits, improving the patient experience, and reducing the threshold for blood sampling. In this study, we aim to validate the capillary microsampling method for olanzapine in comparison to the venipuncture method.

Study objective

Clinical validation of capillary microsampling with finger pricks for olanzapine. The validation method is performed in accordance with the EM guideline. In this process, the analytical methods are assessed for selectivity, carry-over, lower limit of quantification, calibration curve,

accuracy, precision, dilution, matrix effect, and stability

Study design

Cross-sectional observational study

Study burden and risks

Participating in this study will have negligible risk for the patients and during the study the participating patients will have no benefits. When the method is successfully validated, capillary capillary microsampling can be a great benefit to a larger group of patients that use drugs that require TDM.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

- Age 18 to 64
- Treated with olanzapine
- Signed informed consent

Exclusion criteria

- Co-medication: lithium
- Unable to draw blood samples for study purposes
- If the clinician considers the patient to be mentally incompetent in decision making

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-11-2024
Enrollment:	40
Type:	Anticipated

Medical products/devices used

Generic name:	Dried Blood Spot (DBS) testing
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	31-07-2024
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	12-02-2025
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL85836.000.24