pharmacoGenomic gUIDEd persONalized MEDicine: clinical setting

Published: 01-05-2023
Last updated: 16-11-2024

In this study, we aim to evaluate the impact of PGx-guided therapeutic management of hyperpolypharmacy patients using a multidisciplinary approach at Maasstad hospital.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON56044

Source
ToetsingOnline

Brief title
GUIDE ON MED

Condition

- Other condition

Synonym
Hyperpolypharmacy

Health condition

polyfarmacie

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Geriatric and psychiatry, Pharmacogenetics, Pharmacogenomics, Polypharmacy

Outcome measures

Primary outcome

This cross-sectional intervention study aims to situate comprehensive PGx-guided therapeutic management in a clinical setting. To this end, we will quantify the actionable DGIs in a clinical population. Actionable DGIs are defined by the currently known literature (i.e. KNMP, DPWG, PharmVAR, CPIC, and PharmGKB).

Secondary outcome

In addition, the secondary objectives of this study are to evaluate the resulting pharmacotherapeutic optimizations and the adopted recommendations.

Study description

Background summary

Adequate therapeutic management of hyperpolypharmacy patients (concomitant use of >= 10 drugs), improves patient outcomes. There is extensive evidence that pharmacogenetic testing improves therapeutic management and therefore therapeutic outcomes. Over the last 8 years, pharmacogenetic testing has supported therapeutic management at the Maasstad hospital. In previous studies, the clinical impact (ie. symptom improvements, reduction of side effects, and rehospitalization rate) of single and selected combinatory pharmacogenetic testing in psychiatry and primary care has been well described (1-4). However, evaluation of comprehensive pharmacogenetic-guided (PGx-guided) therapeutic management in a complex population, consisting of hospitalized multimorbid patients with hyperpolypharmacy (concomitant use of >= 10 drugs), is limited.

Study objective

In this study, we aim to evaluate the impact of PGx-guided therapeutic management of hyperpolypharmacy patients using a multidisciplinary approach at

Maasstad hospital.

Study design

A cross-sectional intervention study.

Intervention

A comprehensive PGx-guided medication review by a multidisciplinary team and consultation by a clinical pharmacist.

Study burden and risks

Each clinical case will be reviewed by a multidisciplinary team. Recommendations regarding drug selection and dosing options will be given based on PGx results. The recommendations are not binding and clinicians can deviate from the recommendations at all points. Included patients will be subjected to comprehensive targeted PGx screening, using state-of-the-art technologies including Illumina MiSeq sequencing. The PGx screening by blood test consist of a 14-gene panel will examine the genetic variations in a broad spectrum of relevant pharmacogenetics. One single blood draw will be performed next to routinized blood tests and is therefore minimally invasive for the patient. This study hypothesizes that due to the complexity of the hospitalized population consisting of multimorbid and (hyper)polypharmacy patients, PGx-guided medication review will optimize pharmacotherapy in >= 20% of the cases, by providing informed rationales for drug selection and dosing options. As a result of more adequate pharmacotherapy, this will improve patient outcomes and in the course of time result in lower healthcare costs.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- admission to Antes medical psychiatric unit or the internal medicine wards of the Maasstad hospital
- age >= 18 years
- >= 10 systemic drugs (concomitant use)
- medication reconciliation at admission
- informed consent

Exclusion criteria

- previous whole genome genetic testing
- life expectancy < 6 months
- expected admission duration < 5 days (to facilitate acting upon the PGx results)
- if the clinician considers the patient to be mentally incompetent in decision making

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	13-11-2023
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO Date:	01-05-2023
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	20-12-2023
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	19-02-2024
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	NL82587.100.22