Early prediction of adalimumab levels with InsightRx

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Prediction of adalimumab steady-state levels, based on 2 adalimumab levels in the induction phase of therapy with InsightRx.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal inflammatory conditions
Study type	Observational invasive

Summary

ID

NL-OMON49110

Source
ToetsingOnline

Brief title
Early prediction of adalimumab levels with InsightRx

Condition

- Gastrointestinal inflammatory conditions
- Joint disorders

Synonym
Inflammatory Bowel Diseases (M.Crohn and Ulcerative Colitis) and Rheumatic diseases (Rheumatoid Arthritis, Psoriatic Arthritis, Spondyloarthropathy)

Research involving
Human

Sponsors and support

Primary sponsor: Maxima Medisch Centrum
Source(s) of monetary or material Support: wetenschapsfonds MMC

Intervention

Keyword: Adalimumab, InsightRx, Prediction, Therapeutic Drug Monitoring

Outcome measures

Primary outcome

Accuracy of adalimumab level at steady-state prediction, based on early TDM. To numerically quantify the bias and precision, model-predicted levels shall be compared to the observed values in the datasets. MPE (bias) and normalised RMSE (precision) of the individual weighted residuals will be calculated using Microsoft Excel:

Normalised RMSE is RMSE divided by (maximal dependant variable minus minimal dependant variable).

Precise model prediction is defined as MPE and normalised RMSE < 25% (5,6,7).

Secondary outcome

With the newly collected adalimumab levels and anti-adalimumab antibodie titers (and more detailed timing of administration data) new PK parameters will be estimated with NONMEM for both IBD and rheumatic disease population.

Study description

Background summary

Based on cumulative expenses, adalimumab has been the most expensive drug in the Netherlands over the past few years (source: NZA monitor geneesmiddelen in de medisch-specialistische zorg). It is therefore prudent to intervene early in non-responders and adjust dosage to the individual patient. This serves both patient satisfaction and medicines expenses. Target adalimumab trough-levels have been established and TDM is performed in routine clinical practice, late in therapy. Population pharmacokinetic models have been developed and could theoretically be used for early dosage prediction, but these models have not

yet reached clinical practice. There is a need for a user-friendly translation of these population pharmacokinetic adalimumab models into clinical practice to aid in dosing.

Study objective

Prediction of adalimumab steady-state levels, based on 2 adalimumab levels in the induction phase of therapy with InsightRx.

Study design

Observational intervention study

Study burden and risks

Patients will be exposed tot minimal burden in our study.
Patients are required to use a special needlecontainer which sends details on usage (surrogate for adalimumab administration) to the investigator.
Furthermore, patients should collect 3 samples at home through fingerprick for adalimumab TDM which should be sent to the investigator within 24 hours (for stability purposes) clearly marked with date and time af collection

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

All adult patients over 18 years of age with new adalimumab prescriptions at initial dosing interval of 14 days for rheumatic diseases (RA,PsA,SpA) or inflammatory bowel disease (UC, Crohn*s disease) will be eligible to participate in our study.

Exclusion criteria

* Pregnancy
* Previous adalimumab use
* Allergy for adalimumab or excipients (Humira)
* Patients unable or unwilling to consent to participation to this trial

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-03-2019

Enrollment:	40
Type:	Actual

Ethics review

Approved WMO Date:	22-01-2019
Application type:	First submission
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	25-03-2019
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	21-06-2019
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	11-02-2020
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 24282
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL68292.015.18
OMON	NL-OMON24282