Vroege voorspelling adalimumab spiegels met InsightRx

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON24282

Source
NTR

Brief title
EPAL

Health condition

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

Sponsors and support

Primary sponsor: Máxima Medisch Centrum
Source(s) of monetary or material Support: Máxima Medisch Centrum

Intervention

Outcome measures

Primary outcome

Accuracy of adalimumab level at steady-state prediction, based on early therapeutic drug monitoring (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%

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

Background of the study:

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.

Objective of the study:

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 population:

Adult patients with rheumatic diseases and inflammatory bowel disease from Máxima Medisch Centrum and patients with inflammatory bowel disease from Radboud UMC with new adalimumab prescriptions will be recruited

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

Primary study parameters/outcome of the study:

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).

Secundary study parameters/outcome of the study (if applicable):

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.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness (if applicable):

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

Study objective

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

Study design

end of trial

Intervention

None

Contacts

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Eligibility criteria

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 non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-03-2019
Enrollment:	40
Type:	Actual

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion

Date:	31-12-2018
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 49110
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL7450
NTR-old	NTR7692
CCMO	NL68292.015.18
OMON	NL-OMON49110

Study results