Better after Choosing: Randomly allocated or patient preference based treatment with Filgotinib or TNFi in patients with active Rheumatoid Arthritis: the *BACH* study

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primary objectives- To evaluate the actual preference of patients when they decide themselves which mode of action they want to use for treatment of rheumatoid arthritis.- To evaluate differences in treatment satisfaction between patients who choose...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Autoimmune disorders
Study type	Interventional

Summary

ID

NL-OMON52329

Source
ToetsingOnline

Brief title
Better after Choosing: BACH

Condition

- Autoimmune disorders

Synonym
RA, rheuma, rheumatoid arthritis

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Centrum Leeuwarden MCL/ Rheumatology Research Center Northern Netherlands
Source(s) of monetary or material Support: Galapagos,sponsoring met een grant door Galapagos Gilead

Intervention

Keyword: Filgotinib, Rheumatoid Arthritis, Shared decision making, TNF-inhibitors

Outcome measures

Primary outcome

Main study parameter/endpoints:

- the proportion of subjects choosing Filgotinib therapy at baseline

- treatment satisfaction at week 24 at a 5-point Likert scale for current

medical treatment.

Secondary outcome

See section 8.1.2 of the protocol

Group I

- How patients rate being informed by the neutral information video on a Likert

scale of agreement on being well informed, after 6 weeks and at week 24.

- How do patients in the treatment Choice group I rate being in control for

their treatment decision at week 6 and at week 24.

- Proportion of subjects who would choose filgotinib (again or otherwise) at

24-weeks if they were allowed to choose again;

- Proportion of patients who were not able to make a treatment decision.

Total study population:

- Adherence measurements by 5-item Self-Reported Medication Adherence Report Scale (MARS-5) at weeks 0, 6, 12, 18 and 24.
- Change from Baseline of Disease Activity Score (DAS28) and physical activity as measured by SQUASH questionnaire and fitness tracker (daily footsteps, speed of acceleration, mean heart beat) at weeks 6, 12 and 24.
- Time to remission by both PROMs and DAS28 (with remission defined as DAS28 <2.6). And a comparison of percentage of remission for Group I JAKi- and TNFi-, Group II JAKi- and TNFi-subgroups at weeks 6, 12, 18, 24.
- Change from baseline in Health Assessment Questionnaire Disability Index (HAQ-DI) at week 12 and 24.
- Change from baseline in Work Productivity and Activity Impairment (WPAI) at Weeks 6, 12, and 24.
- Registration of concomitant medication use (NSAIDs, analgesics, other DMARDs, i.a. and i.m. corticosteroid injections).
- Weekly number of footsteps and improvement of DAS28 at the next visit
- Actual preference of the treating rheumatologists when they decide which mode of action for treatment of each rheumatoid arthritis patient they would have chosen: Percentages of either filgotinib or TNFi.
- To evaluate which factors contribute to a difference in treatment choice between patient and rheumatologist (mode of administration, comorbidity, side effects, patient-peer information)

Patient characteristics will be evaluated to describe the population and use as covariables in statistical analysis or to calculate disease activity scores.

See section 8.1.3 of the protocol

Study description

Background summary

Despite their efficacy in the treatment of Rheumatoid Arthritis and their partial advantage over traditional bDMARDs, JAK inhibitors (JAKi or tsDMARDs) have not gained preference over Tumor Necrosis Factor inhibitors (TNFi) in guidelines or clinical practice. The biggest influence on recent guidelines has been the *Treat To Target* principle (T2T), in which shared decision making plays a key part. Patient preference has proven to be a large barrier in treatment adjustments (14- 37%).

While patients showed better adherence and higher treatment satisfaction when engaged in shared decision making. From survey studies it is suggested that patient preference and satisfaction will be in favour of oral JAK inhibitors over parenteral biologics. We want to evaluate the treatment preference of patients when they are given the opportunity to choose between oral treatment with the JAKi Filgotinib and subcutaneous injections TNFi. The study also compares the difference in treatment satisfaction between patients who can choose their own treatment and patients who are randomized to the same treatment options.

In addition to higher treatment satisfaction and better adherence, we expect to find an improvement in DAS28-, HAQ-, SQUASH- and WPAI-scores and also an improved activity and work productivity.

Study objective

primary objectives
- To evaluate the actual preference of patients when they decide themselves which mode of action they want to use for treatment of rheumatoid arthritis.
- To evaluate differences in treatment satisfaction between patients who choose their own therapy and those patients that are randomized to the same treatment options.

secondary Objectives:
Group I:
- To evaluate how patients rate being informed by the neutral information video on a Likert scale of agreement on being well informed, at week 6 and at week 24.
- How do patients in the treatment Choice group I rate being in control for their treatment decision at week 6 and at week 24.

Total study population:
- To evaluate if therapy adherence is increased when patients are allowed to decide their own therapy compared to patients who are randomized to the same treatment options.
- To evaluate the difference in improvement of disease activity by the Disease Activity Score (DAS28) and physical activity as measured by SQUASH questionnaire and fitnesstracker (pedometer, accelerometer, heart beat).
- To compare time to remission for Group I and II, and for TNFi users in the Choice group and those in the Randomization group and between JAKi users in the Choice group and those in the Randomization group.
- To compare the difference in improvement of the objective components of the DAS 28 (SJC, CRP/ BSE) to the improvement in the (more) subjective components; VAS or TJC.
- To compare adherence to medication between Choice and Randomization groups.
- Compare adherence to medication between TNFi users in the Choice group and those in the Randomization group and between JAKi users in the Choice group and those in the Randomization group.
- To evaluate the weekly reported number of footsteps as an early predictor of improvement of DAS28 at the next visit
- To evaluate the difference in improvement of HAQ , WPAI and SF-36 scores with physical activity as measured by SQUASH and fitness tracker (pedometer, accelerometer, heart beat).
- To evaluate the actual preference of the treating rheumatologists when they decide which mode of action for treatment of each rheumatoid arthritis patient they would have chosen.
- To evaluate which factors contribute to a difference in treatment choice between patient and rheumatologist (comorbidity, personal preference, hospital preference for TNFi)

Study design

This multicenter study with a 24-week treatment period is designed to evaluate the treatment preference of patients when they are given the opportunity to choose between oral treatment with the JAKi Filgotinib and subcutaneous injections TNFi. The study also compares the difference in treatment satisfaction between patients who can choose their own treatment and patients who are randomized to the same treatment options.

BACH is an open label trial with a total of 100 patients. 50 patients will be randomized for to two treatment options (JAKi or TNFi) and another 50 can choose their treatment out of the same options.

This study will have a multicenter design in the Netherlands. Adult patients with active RA who had insufficient therapeutic effect on a conventional DMARD (csDMARD non-responders) or who have a contra-indication to a csDMARD visiting the outpatient rheumatology clinics of the participating centers will be

invited to participate in the study.

Intervention

100 patients will be randomized into two groups of 50 patients:
Group I: N=50 subjects are given the choice between treatment with Filgotinib (one oral tablet once daily 200 mg) or TNFi (one subcutaneous injection Adalimumab 40 mg every two weeks or one subcutaneous injection etanercept 50 mg every week, depending on hospital policy of the individual centers)
Group II: N= 50 subjects who will be randomized for the same treatment options as group I: treatment with Filgotinib (one oral tablet once daily 200 mg) or TNFi (one subcutaneous injection Adalimumab 40 mg every two weeks or one subcutaneous injection etanercept 50 mg every week, depending on hospital policy of the individual centers)

**conform regular care: if a patient is > 75 and or has an eGFR < 60 a dose reduction of filgotinib to 1 dd 100 mg has to follow

Study burden and risks

All medication is prescribed at the indicated dosages used in clinical care, according to international guidelines.
Study burden and risks are deemed acceptable and similar to daily clinical care:
- questionnaires will take about 10-30 minutes to complete (depending on the visit).
- DAS 28 joint score is standard RA care
- blood withdrawal will be as in normal clinical practice while starting TNFi or JAKi

Contacts

Public
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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Demographic and general characteristics:
- Adult male or female patients, 18-65 years of age.
- Able and willing to give written informed consent.
- Have sufficient knowledge of the Dutch language to be able to comply with the requirements of the study protocol.

Inclusion criteria:
- Diagnosis of adult-onset RA as defined by the 2010 ACR/ EULAR Rheumatoid arthritis classification criteria;
- Diagnosis of RA for >= three months;
- Are being treated >= three months with >= 1 csDMARD therapy;
- Have had an inadequate response or intolerance to at least 1 csDMARD;
- Have moderately to severely active RA to the discretion of the rheumatologist or defined as a DAS28 >= 3.2 at screening and baseline visits;
- - Subjects must have been on a stable dose of csDMARD therapy (restricted to methotrexate, chloroquine, hydroxychloroquine, sulfasalazine, or leflunomide or low dose prednisone) for >= 4 weeks prior to the baseline visit. An IM corticosteroid injection or tapering schedule at the start of the study (because the patients arthritis might otherwise be too severe for too long) is not encouraged but considered to be at the discretion of the local PI and can be discussed with the studyteam.

Exclusion criteria

- Previous treatment with any biological DMARD or targeted synthetic DMARD/JAKi;
- Inflammatory rheumatic disease other than RA, except for secondary Sjögren*s syndrome.

- Having a contraindication for either TNFi or filgotinib;
- Significantly increased risk of major cardiovascular problems (such as heart attack or stroke)
- Current smoker or have done so for a long time in the past
- significantly increased risk of cancer
- Latent or active tuberculosis;
- Active or recurrent infections;
- History of any malignancy within 5 years except for successfully treated NMSC or localized carcinoma in situ of the cervix;
- >= 3x upper limit of normal ALT, AST;
- eGFR <= 30 ml/min;
- planned or actual pregnancy or planning to father a child.

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	26-05-2021
Enrollment:	100
Type:	Actual

Medical products/devices used

Generic name:	activity tracker
Registration:	Yes - CE outside intended use

Ethics review

Approved WMO Date:	08-04-2021
Application type:	First submission
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)
Approved WMO Date:	07-06-2021
Application type:	Amendment
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)
Approved WMO Date:	12-08-2021
Application type:	Amendment
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)
Approved WMO Date:	20-12-2021
Application type:	Amendment
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)
Approved WMO Date:	02-01-2023
Application type:	Amendment
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)
Approved WMO Date:	28-08-2023
Application type:	Amendment
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)

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	NL76371.099.21