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Norwegian Very Early Arthritis Clinic (NOR-VEAC): spectrum of arthritides, disease course and predictors of outcomes

Submission date
31/01/2011

Recruitment status
No longer recruiting

Registration date
07/04/2011

Overall study status
Completed

Last Edited
24/01/2018

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Arthritis is a common condition that causes joint pain and inflammation. This is an observational study following the disease course and treatment of four groups of patients who have been recently diagnosed with arthritis.

Who can participate?
Group 1: Patients aged 18 - 75 with arthritis in at least two joints of less than 16 weeks duration
Group 2: Patients aged 18 - 75 with rheumatoid arthritis of less than 12 months duration
Group 3: Patients aged 18 - 75 with any arthritis of less than 12 months duration who test positive for rheumatoid factor and anti-CCP (a blood test)
Group 4: Patients in group 2 and 3 who start treatment with a disease-modifying anti-rheumatic drug (DMARD)

What does the study involve?
At the start of the study all participants' arthritis symptoms are assessed. Pain and fatigue, employment status, current treatment and changes in treatment are also recorded, and urine and blood samples are taken. Patients in group 1 have follow-up assessments at 3, 6, 9, 12, 18, 24 months, and then every 6 months up to 5 years. Follow-up assessments are stopped if the patient does not have any joint swelling on two consecutive visits. Patients in group 2 and 3 have follow-up assessments at 3, 6, 9, 12, 18, and 24 months, and then every 6 months up to 5 years. Patients in group 4 have monthly follow-up assessments until they have reached the treatment target (disappearance of symptoms [remission]) at two consecutive visits. They are then followed as group 2 and 3 up to 5 years. If the disease returns, follow-up is intensified with monthly assessments until the target has been reached again.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
Diakonhjemmet Hospital (Norway)

When is the study starting and how long is it expected to run for?
August 2010 to December 2021

Who is funding the study?
1. Southern and Eastern Norway Regional Health Authority (Norway)
2. Norwegian Foundation for Health and Rehabilitation (Norway)
3. Abbott Norge AS (Norway)

Who is the main contact?
Prof Tore Kristian Kvien
t.k.kvien@medisin.uio.no

Contact information

Type(s)
Scientific

Contact name
Prof Tore Kristian Kvien

Contact details
Department of Rheumatology
Diakonhjemmet Hospital
P.O. Box 23
Vinderen
Oslo
Norway
0319
-
t.k.kvien@medisin.uio.no

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
A longitudinal observational multicentre cohort study of the spectrum of arthritides, disease course and predictors of outcomes: The Norwegian Very Early Arthritis Clinic (NOR-VEAC) study

Acronym
NOR-VEAC

Study objectives
Early identification of patients at risk of developing rheumatoid arthritis (RA) and treat-to-target strategy/tight control of treatment in patients not in remission has become the new paradigm in rheumatology. We aimed at applying these principles in patients with recent onset synovitis in the setting of a very early arthritis clinic.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Regional Committee for Medical and Health Science Related Research Ethics South-East Region, 15/04/2010, ref: 2010/719

Study design
Longitudinal observational multicentre cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Rheumatoid arthritis/undifferentiated arthritis

Interventions
Baseline:
Data at baseline for all enrolled patients who sign informed consent:
1. Age
2. Gender
3. Years of education
4. Smoking (never, previous, current daily smoker)
5. Presumed diagnosis
6. Time of onset of first swollen joint
7. IgM rheumatoid factor (level)
8. Cyclic citrullinated peptide antibody (a-CCP) (level)
9. Erosive disease (yes/no)
10. Co-morbidity (checklist and questionnaire for cardiovascular disease)
11. Body mass index (BMI)

Fulfillment of new and old RA criteria, as well as classification criteria for spondyloarthritis (ASAS) and psoriatic arthritis (CASPAR) will be recorded. Joint assessment (66 swollen, 28 tender) with calculated joint counts, pain and fatigue (100 mm VAS), patient global assessment (100 mm VAS), physician global assessment (100 mm VAS), HAQ, RAID, ESR, CRP, EQ-5D, employment status (work disability, indirect costs), current treatment and change in treatment. Serum, urine, and blood for biobank.

Follow-up:
Patients in group 1 will have follow-up examinations at 3, 6, 9, 12, 18, 24 months, and then every 6 months up to 5 years. Follow-up examinations will be terminated if the patient on two consecutive visits does not have any joint swelling.

Patients in group 2 and 3 will have follow-up examinations at 3, 6, 9, 12, 18, and 24 months, and then every 6 months up to 5 years.

Patients in group 4 (starting with DMARDs) will have monthly follow-up examinations until they have reached the predefined treatment target at two consecutive visits (remission, DAS28 less than 2.6). They will then be followed as group 2 and 3 up to 5 years. If a disease flare occurs (DAS28 greater than 2.6), the follow-up program will again be intensified with monthly examinations until the target again has been reached. The treatment program will be according to the new EULAR recommendations for use of synthetic and biological DMARDs. If DAS 28 is persistently elevated greater than 2.6 but driven by other factors than inflammation (eg tender joints), and the patient is in remission by clinical judgement (e.g. no swollen joints), less frequent assessments can be permitted.

Assessments:
The following assessments will be performed at the main visits (3, 6, 9, 12, 18, 24 months and then every 6 months up to 5 years): Joint assessment (66 swollen, 28 tender) with calculated joint counts, pain and fatigue (100 mm VAS), patient global assessment (100 mm VAS), physician global assessment (100 mm VAS), HAQ, RAID, ESR, CRP, EQ-5D, employment status (work disability, indirect costs), current treatment and change in treatment.

At yearly visits, patients in group 1 will be reassessed for fulfillment of classification criteria (RA [2010 ACR/EULAR], SpA [ASAS], PsA [CASPAR]).

The following assessments will be performed at the monthly visits between the main 3-month visits: Joint counts (28 joints), patient global VAS and ESR/CRP with calculation of DAS28.

The following additional assessments will be performed at baseline and after 3, 6, and 12 months and then annually: Imaging (conventional radiographs hands and feet, MRI dominant hand (selected centers)) as well as serum and urine for research biobank.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure

Measured yearly throughout the study:
1. Development of rheumatoid arthritis or other specific inflammatory arthritic disease according to established classification criteria
2. Development of erosive arthritis

Secondary outcome measures
Measured at study end:
1. Achievement of stable remission of disease activity
2. Health status
3. Quality of life/utility
4. Indirect costs

Overall study start date
23/08/2010

Completion date
31/12/2021

Eligibility

Key inclusion criteria
Group 1:
1. Patients of both genders
2. Aged 18 - 75 years
3. Patients with arthritis in at least 2 peripheral joints of less than 16 weeks duration (onset of arthritis is defined as the time when at least one joint became swollen)

Group 2:
1. Patients of both genders
2. Aged 18 - 75 years with RA according to the 2010 American College of Rheumatology /European League Against Rheumatism (ACR/EULAR) criteria
3. Patients with arthritis of less than 12 months duration (onset of arthritis is defined as the time when at least one joint became swollen)
Group 3: Patients of both genders aged 18 - 75 years with any arthritis (including monoarthritis) of less than 12 months duration with presence of positive anti-CCP and/or rheumatoid factor. Onset of arthritis is defined as the time when at least one joint became swollen.
Group 4: Patients in group 2 and 3 who start treatment with a disease modifying anti-rheumatic drug (DMARD)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex

Both

Target number of participants
2000

Key exclusion criteria
Patients with the following reasons for joint swelling will be excluded from follow-up:
1. Osteoarthritis
2. Trauma
3. Mechanical joint lesion (e.g. meniscus lesion)
4. Gout
5. Pseudogout
6. Septic arthritis
7. Acute sarcoid arthropathy

If any of these conditions are diagnosed during the course of the study, patients will be excluded from further follow-up.

Date of first enrolment
23/08/2010

Date of final enrolment
01/03/2016

Locations

Countries of recruitment
Norway

Study participating centre
Diakonhjemmet Hospital
Oslo
Norway
0319

Sponsor information

Organisation
Diakonhjemmet Hospital (Norway)

Sponsor details
c/o Tore Kristian Kvien
Department of Rheumatology
P.O. Box 23
Vinderen

Oslo
Norway
0319
-
t.k.kvien@medisin.uio.no

Sponsor type
Hospital/treatment centre

Website
http://www.diakonsyk.no

ROR
https://ror.org/02jvh3a15

Funder(s)

Funder type
Industry

Funder Name
Southern and Eastern Norway Regional Health Authority (Norway)

Funder Name
Norwegian Foundation for Health and Rehabilitation (Norway)

Funder Name
Abbott Norge AS (Norway) - unrestricted research grant

Results and Publications

Publication and dissemination plan
Planned publication of interim results in a high impact peer reviewed journal by 01/06/2018.
Planned publication of final results in a high impact peer reviewed journal by 01/01/2023.

Intention to publish date
01/01/2023

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary

Data sharing statement to be made available at a later date