

Assessment of the test characteristics of an instant anti-CCP2 test compared to the anti-CCP2 elisa in serum

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-What are the test characteristics of an anti-CCP2 quicktest (sensitivity, specificity, positive and negative predictive value, kappa statistics) using capillary or venous blood compared to the golden standard, the anti-CCP2 Elisa in serum?-What...

Ethical review	Approved WMO
Status	Pending
Health condition type	Synovial and bursal disorders
Study type	Observational invasive

Summary

ID

NL-OMON30010

Source

ToetsingOnline

Brief title

Test characteristics of an instant anti-CCP2 test

Condition

- Synovial and bursal disorders

Synonym

arthritis, Reumatoid Arthritis

Research involving

Human

Sponsors and support

Primary sponsor: Sint Maartenskliniek

Source(s) of monetary or material Support: Ministerie van OC&W, Eurodiagnostics, Arnhem

Intervention

Keyword: anti-CCP, diagnostic, early arthritis

Outcome measures

Primary outcome

Results from the anti-CCP2 quicktest with capillary and venous blood are compared to each other and to the anti-CCP2 elisa in serum using dichotomous and trichotomous distributions (negative, weakly positive and positive (3*3 table) or positive and negative (2*2) table). Test characteristics are described using sensitivity, specificity, positive and negative predictive value.

Secondary outcome

Pragmatic aspects including needed time, feasibility and the percentage of failed tests are described qualitatively and quantitatively.

Study description

Background summary

Recently a new diagnostic test for Rheumatoid Arthritis has been developed - the anti-CCP2 test - which is as sensitive (60%) but more specific for RA (95%) compared to rheumatoid factor. The additional value of anti-CCP2 has been established in prospective studies.

The presence of anti-CCP antibodies is measured using an Elisa, which takes a few days. If a quicktest for anti-CCP2 was available, this could decrease delay of diagnosis and treatment. Recently a 5 minute anti-CCP2 test has been developed that can be used on capillary or venous blood.

Study objective

- What are the test characteristics of an anti-CCP2 quicktest (sensitivity, specificity, positive and negative predictive value, kappa statistics) using capillary or venous blood compared to the golden standard, the anti-CCP2 Elisa in serum?
- What are pragmatic aspects of this test, including average needed time,

percentage number of failed tests, feasibility.

Study design

Two anti-CCP2 quicktests will be done on RA patients at their home or at the outpatient clinic. Both venous blood and capillary blood will be drawn. Results for each test are noted as well as pragmatic aspect and baseline, medication and RA related data.

Study burden and risks

The Burdon for the patient include sampling of venous blood and capillary blood ("finger prick") and providing some baseline data. Time required is once 10 minutes and there are no associated risks bu a bruise from the venous blood sampling. The anti-CCP2 status is already known for all patients, so they do not receive new disease information.

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

Rheumatoid arthritis

informed consent given

Aerea of Nijmegen

Previous Anti-CCP2 status determined

Exclusion criteria

none

Study design

Design

Study type: Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status: Pending

Start date (anticipated): 01-09-2006

Enrollment: 160

Type: Anticipated

Ethics review

Approved WMO

Application type: First submission

Review commission: CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL13564.091.06