Technology Offer

Manual ELISA based on hnRNP A3 related Peptides for Early Diagnosis of Rheumatoid Arthritis

Ref. No.: CH370 / CH787

Background

Rheumatoid Arthritis (RA) is an autoimmune disease in which the body´s immune system attacks the joint cartilage. The worldwide prevalence is 0,5-1% of adults, with 5-50 per 100 000 newly developing the condition per year. The disease progresses very rapidly in the first few months. Clinical studies have shown that very good therapy success and response rate can be achieved if suitable active compounds are used already in the early stages of the disease. Therefore, the early diagnosis and early treatment start is of strong medical interest. Currently the predominantly used serological marker for diagnosing RA are the rheumatoid factor ("RF", subgroup of immunoglobulins) and antibodies against the cyclic citrullinated peptide (CCP). However, RF is not a reliable marker, as RF is also detectable in patients with infectious and other diseases as well as in some healthy patients. Further on, up to 40% of early RA patients are anti-CCP-negative and/or RF-negative, so that not all RA patients can be diagnosed so far by commonly used *in vitro* diagnostics.

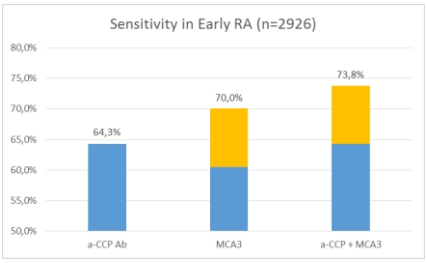

Fig. 1: Test sensitivity of anti-CCP ELISA, of the new test based on three hnRNPA3 peptides (MCA3) and of both test combined, using the Early RA cohort EIRA (N= 2926). Yellow: anti-CPP Ab negative patients. Blue: anti-CPP Ab positive patients

Technology

Novel five citrullinated hnRNP A3 mutated peptides have been found to be good candidates for the diagnosis of RA. Already in early stages of RA, patients develop autoantibodies against hnRNP A3 related peptides which can be detected by test systems using these peptides. The diagnostic value has been validated in studies with the known Swedish EIRA cohort of early RA patients (N=2926; thereof 1881 anti-CCP positive, 1045 anti-CCP negative) with a protein microarray) and with a Charité patient cohort (N= 150, control N= 375), in-house ELISA). Using 2 or 3 of the new peptides, 70% of early RA patients can be detected (6% more as if CCP2-ELISA alone is used) and 82% of patients with established RA. Further on 27% of the anti-CCP- negative RA-patients can be identified. If results of the new test are combined with CCP-ELISA test results, 4,7% more patients with established and 9,5% more patients with early RA can be detected. Now an optimized ELISA has been developed with all five hnRNP-A3 peptides within one well.

Benefits

- ✓ 6% more patients with early RA can be identified (70%) as with anti-CCP2 ELISA alone (64%)
- ✓ 9,5% more early RA patients detectable if both tests are combined
- ✓ Identification of RA-patients within anti-CCP serum negative patient pool
- ✓ 4,7% more patients with established RA can be recognized if novel test is combined with anti-CCP-Elisa as if anti-CCP is tested alone

Application

Diagnosis of early RA and of anti-CCP-negative RA patients

Commercial Opportunity

Searching for a licensing partner for manual ELISA commercialization

Key words

hnRNPA3 related peptides, rheumatoid arthritis, ELISA, diagnostic, early rheumatoid arthritis, anti-CCP negative, serum

Developmental Status

ELISA prototype with five hnRNP A3 related peptides

IP Status

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Further invention in progress for patenting

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