Serum soluble vascular cell adhesion molecule-1 overexpression is a disease marker in patients with first-time diagnosed antinuclear antibodies: a prospective, observational pilot study (sVCAM-1 in ANA-positive patients)

First published: 04/01/2018

Last updated: 31/03/2024

Study Finalised

Administrative details

EU PAS number

EUPAS22154

Study ID

22155

DARWIN EU® study

No

Study countries

Germany

Study description

Objective: Antinuclear antibodies (ANA) serve as screening tests for connective tissue diseases but have low specificity. In this pilot study we aimed to identify patients with first-time positive ANA and musculoskeletal complaints, and correlate serum soluble vascular adhesion molecules as biomarkers.Methods: Prospective, observational study with 100 ANA-positive patients, comparing them to age- and gender-matched healthy controls (HC, n=75). Serum levels of soluble intercellular adhesion molecule-1 (sICAM-1), endothelial-leukocyte adhesion molecule-1 (sELAM-1), and vascular cell adhesion molecule-1 (sVCAM-1) were measured. A subgroup of patients with systemic sclerosis (SSc) treated with immunosuppressants was followed over 10 months.Results: Patients belonged to three main entities: Rheumatoid arthritis (RA, n=32), collagen diseases (CD, n=56) also including systemic sclerosis (SSc, n=11), and other autoimmune diseases (n=12). sICAM-1 was similar among groups. sELAM-1 was elevated by 1.9-fold in only in SSc. sVCAM-1 was elevated by 3.1-fold in RA, by 3.3-fold in CD, and other autoimmune diseases by 3.4-fold. 7 SSc-patients with immunosuppression had a 2.7-fold increased sVCAM-1 at baseline and reached the levels of healthy controls after 5 months, while CRP, ESR and clinical parameters remained unchained. Conclusion: This study suggests that sVCAM-1 is a disease marker independent from standard serum parameters in several rheumatic diseases.

Study status

Finalised

Research institutions and networks

Institutions

Dr. Mara Oleszowsky

Contact details

Study institution contact

Mara Oleszowsky info@rheumatologiepraxis-koeln.de

Study contact

info@rheumatologiepraxis-koeln.de

Primary lead investigator

Mara Oleszowsky

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 02/01/2012

Study start date

Actual: 02/01/2012

Data analysis start date

Actual: 02/01/2012

Date of interim report, if expected

Actual: 02/01/2012

Date of final study report
Actual: 04/01/2018

Sources of funding

- Other
- Pharmaceutical company and other private sector

More details on funding

Actelion, UNI Bonn

Study protocol

sVCAM-1 Scleroderma MFS 04.1.2018 4259.pdf (488.77 KB)

Regulatory

Was the study required by a regulatory body?

No

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Other

Study topic, other:

Diagnostic procedure- Antinuclear antibodies (ANA) screening to measure serum levels of soluble intercellular adhesion molecule-1 (sICAM-1), endothelial-leukocyte adhesion molecule-1 (sELAM-1), and vascular cell adhesion molecule-1 (sVCAM-1)

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Effectiveness study (incl. comparative)

Data collection methods:

Primary data collection

Main study objective:

Antinuclear antibodies (ANA) serve as screening tests for connective tissue diseases but have low specificity. In this pilot study we aimed to identify patients with first-time positive ANA and musculoskeletal complaints, and correlate serum soluble vascular adhesion molecules as biomarkers.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Case-series

Population studied

Short description of the study population

Antinuclear antibodies (ANA)-positive patients defined as a titer of at least 1:160.

Age groups

- Adults (18 to < 46 years)
- Adults (46 to < 65 years)
- Adults (65 to < 75 years)
- Adults (75 to < 85 years)
- Adults (85 years and over)

Special population of interest

Immunocompromised

Estimated number of subjects

100

Study design details

Outcomes

This study suggests that sVCAM-1 is a disease marker independent from standard serum parameters in several rheumatic diseases.

Data analysis plan

Prospective, observational study with 100 ANA-positive patients, comparing them to age- and gender-matched healthy controls (HC, n=75). Serum levels of soluble intercellular adhesion molecule-1 (sICAM-1), endothelial-leukocyte adhesion molecule-1 (sELAM-1), and vascular cell adhesion molecule-1 (sVCAM-1) were measured. A subgroup of patients with systemic sclerosis (SSc) treated with immunosuppressants was followed over 10 months.

Data management

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

Data sources

Data sources (types)

Other

Data sources (types), other

Prospective patient-based data collection

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

Unknown