

Very early steroid therapy in arthritis - the Stop Arthritis Very Early (SAVE) trial

Submission date 24/11/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 10/03/2006	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 14/07/2014	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
2004-000803-17

Protocol serial number
Study protocol - version IX, EudraCT number

Study information

Scientific Title

Acronym

SAVE

Study objectives

The primary hypothesis underlying this clinical trial is that in patients with early inflammatory arthritis, one intramuscular injection with 120 mg of methyl-prednisolone (depot formula) will result in 10 to 15% more clinical remissions compared to one placebo injection

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved by the Internal Review Boards and Ethical Committees of the Vienna Medical University and all other participating centres on 20/10/2003, reference number 350/2003

Study design

Randomized placebo-controlled multicentre clinical trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Early arthritis with a symptom duration of less than four months

Interventions

Patients allocated to the corticosteroid group will receive one intramuscular injection of methyl-prednisolone (120 mg depot-formulation such as depomedrol or equivalent) at baseline. Patients allocated to the placebo group will receive one intramuscular injection with isotonic saline.

Follow-up is for a maximum of one year.

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Methyl prednisolone

Primary outcome(s)

The primary outcome will be the presence of clinical remission both at week 12 and at one year

Key secondary outcome(s)

Secondary outcome measures include all core-set measures for clinical trials in rheumatoid arthritis (RA), as well as the use of NSAIDs and dosage

Completion date

01/07/2007

Eligibility

Key inclusion criteria

Newly referred patients with:

1. Arthritis of at least one joint (out of 66 possible joints)
2. A duration of symptoms of inflammatory arthritis of 16 weeks at most
3. No pre-treatment with steroids for this indication
4. No pre-treatment with a coxib for this indication

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. Patients under 18 years
2. Patients with joint swelling due to trauma
3. Patients with only distal interphalangeal (DIP) arthritis
4. Patients with suspected or proven septic arthritis or gout
5. Patients requiring oral anticoagulant therapy precluding intramuscular injections
6. Patients who are pregnant
7. Patients with a contraindication for paracetamol
8. Severe liver function failure (Child-Pugh >9)
9. Significantly impaired kidney function (creatinine >1.8 mg/dl)
10. Gilbert-Meulengracht's syndrome
11. Patients with a contraindication for Non Steroidal Anti-Inflammatory Drugs (NSAIDs) and/or coxibs
12. A history of sulfonamide allergy
13. Active gastric or duodenal ulcer or gastrointestinal bleeding
14. A history of exacerbation of asthma, urticaria, or angioedema following NSAID or aspirin intake
15. Severe liver function failure (Child-Pugh >9)
16. Significantly impaired kidney function (creatinine >1.8 mg/dl)
17. Severe heart failure

Date of first enrolment

01/01/2004

Date of final enrolment

01/07/2007

Locations

Countries of recruitment

Austria

Lithuania

Mexico

Study participating centre

Vienna Medical University

Vienna

Austria

A-1090

Sponsor information

Organisation

Vienna Medical University (Austria)

ROR

<https://ror.org/05n3x4p02>

Funder(s)

Funder type

Research organisation

Funder Name

European League Against Rheumatism (EULAR) grant

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/03/2010		Yes	No
Results article	results	01/08/2013		Yes	No