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

| Submission date | Recruitment status | [ ] Prospectively registered |
|---|---|---|
| 24/11/2005 | No longer recruiting | [ ] Protocol |
| **Registration date** | **Overall study status** | [ ] Statistical analysis plan |
| 10/03/2006 | Completed | [X] Results |
| **Last Edited** | **Condition category** | [ ] Individual participant data |
| 14/07/2014 | Musculoskeletal Diseases | |

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

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## Additional identifiers

**EudraCT/CTIS number**
2004-000803-17

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**

# 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

### Secondary study design
Randomised controlled trial

### Study setting(s)
Not specified

### Study type(s)
Treatment

### Participant information sheet

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

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

### Overall study start date
01/01/2004

### 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

### Age group
Adult

### Sex
Both

### Target number of participants
400

### 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
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## Sponsor information

### Organisation
Vienna Medical University (Austria)

### Sponsor details
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### Sponsor type
University/education

### ROR
https://ror.org/05n3x4p02

## Funder(s)

### Funder type
Research organisation

### Funder Name
European League Against Rheumatism (EULAR) grant

## Results and Publications

### Publication and dissemination plan
Not provided at time of registration

### Intention to publish date

### 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 |