

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

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

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

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## Additional identifiers

### Clinical Trials Information System (CTIS)

2004-000803-17

### Protocol serial number

Study protocol - version IX, EudraCT number 2004-000803-17

## 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?
<a href="#">Results article</a>	results	01/03/2010		Yes	No
<a href="#">Results article</a>	results	01/08/2013		Yes	No