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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