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Assessment of safety, pharmacokinetics and efficacy in a combination treatment with SMP-114

Submission date 15/02/2006	**Recruitment status** Stopped	[X] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 23/02/2006	**Overall study status** Stopped	
Last Edited 10/09/2019	**Condition category** Musculoskeletal Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT00296257

Protocol serial number
D2450174

Study information

Scientific Title
A phase II, multicentre, randomised, double-blind, placebo-controlled study evaluating the efficacy, safety and pharmacokinetics of two doses of a candidate disease modifying anti-rheumatic drug (DMARD) (SMP-114, 120 mg and 240 mg once daily) administered in combination with ongoing methotrexate treatment in patients with active rheumatoid arthritis

Acronym
ASPECTS

Study objectives
SMP-114 in combination with methotrexate is more efficacious than methotrexate alone.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Local medical ethics committee (UK) , 29/01/2006, ref: 05/Q0501/170

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Rheumatoid arthritis (RA)

Interventions
SMP-114 (120 mg and 240 mg) in combination with methotrexate compared to methotrexate alone.

Intervention Type
Drug

Phase
Phase II

Drug/device/biological/vaccine name(s)
SMP-114, methotrexate

Primary outcome(s)
The efficacy of SMP-114 (120 mg and 240 mg) versus placebo in terms of the percentage of patients meeting the ACR criteria for 20% improvement in RA (ACR20) at week 24.

Key secondary outcome(s)
1. The efficacy of SMP-114 (120 mg and 240 mg) versus placebo after 24 weeks in terms of:
1.1. ACR50

1.2. ACR70
1.3. Disease Activity Score-28 (DAS28)
1.4. European League Against Rheumatism (EULAR) response
2. The efficacy of SMP-114 versus placebo in terms of change in:
2.1. Core variables
2.2. Time to response
2.3. Quality of life
2.4. Radiological measurements of joint damage
2.5. Assessment of safety and tolerability
2.6. Pharmacokinetics (PK) measurements

Completion date
21/07/2008

Eligibility

Key inclusion criteria
1. Male or female patients aged at least 18, with rheumatoid arthritis (RA) for a minimum of six months
2. Has been receiving methotrexate treatment (stable for eight weeks)
3. Has active disease classified as American College of Rheumatology (ACR) functional class of I, II or III

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Has previously discontinued DMARD therapy due to hepatic intolerance
2. Has received any DMARD in addition to methotrexate during the four weeks prior to randomisation
3. Is receiving more than two DMARDs in addition to methotrexate at the time of screening
4. Is receiving or has received gold, leflunomide or biological agents including tumour necrosis factor (TNF) or Interleukin 1 (IL-1) inhibitors within the eight weeks prior to randomisation
5. Has previously failed two or more DMARDS

Date of first enrolment
28/02/2006

Date of final enrolment
13/07/2007

Locations

Countries of recruitment
United Kingdom

England

Czech Republic

Germany

Hungary

Netherlands

Poland

Study participating centre
Dainippon Sumitomo Pharma Europe Ltd (UK)
London
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Sponsor information

Organisation
Dainippon Sumitomo Pharma Europe Ltd (UK)

ROR
https://ror.org/03sh4z743

Funder(s)

Funder type
Industry

Funder Name
Dainippon Sumitomo Pharma Europe Ltd (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary