ISRCTN54813778 https://doi.org/10.1186/ISRCTN54813778

A double-blind placebo-controlled pilot study of safety and tolerability of AIMSPRO® in established diffuse cutaneous systemic sclerosis

Submission date
07/10/2008

Recruitment status
No longer recruiting

Registration date
24/10/2008

Overall study status
Completed

Last Edited
27/09/2013

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] 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

ClinicalTrials.gov (NCT)
NCT00769028

Protocol serial number
DISS01

Study information

Scientific Title

Study objectives
That the hyperimmune caprine serum medication AIMSPRO® will be a safe and well tolerated therapy for patients with established diffuse cutaneous systemic sclerosis.

As of 18/08/2011 the anticipated end date of this trial has been refined, and the following end dates are now accurate:
Double-blind phase end date: September 2011
Open-label phase end date: October 2011

Ethics approval required
Old ethics approval format

Ethics approval(s)
This study was approved by the National Research Ethics Committee, Royal Free Hospital NHS Trust on 30/07/2008 (ref: 08/H0720/63).

Primary study design
Interventional

Study design
Treatment, parallel-assignment, double-blind (subject, caregiver, investigator, outcomes assessor), randomised, placebo-controlled, safety/efficacy trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Diffuse cutaneous systemic sclerosis

Interventions
AIMSPRO® (manufactured by Sypharma Pty Ltd, Australia) 1.0 ml twice weekly for 6 months, injected sub-cutaneously vs placebo.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
AIMSPRO®

Primary outcome(s)
Modified Rodnan Skin Score at 0, 6 and 26 weeks.

Key secondary outcome(s)
The following will be assessed at 0, 6 and 26 weeks:
1. Scleroderma Health Assessment Questionnaire
2. Scleroderma UK functional score
3. Patient and Physician Global Assessment
4. SF-36 Health Survey
5. Medical Research Concil (MRC) Sum Score

Completion date
01/08/2011

Eligibility

Key inclusion criteria
1. Males and females aged 18 years and older
2. Must fulfil 1980 preliminary classification criteria for systemic sclerosis of the American Rheumatism Association
3. Diffuse cutaneous systemic sclerosis, as evidenced by skin sclerosis proximal to the elbows or knees and absence of the anti-centromere autoantibody
4. Three years must have elapsed since the first non-Raynaud's manifestation
5. Men and women of chilbdearing potential must use adequate birth control measures for the duration of the study and should continue such precautions for six months after receiving the last injection of AIMSPRO®
6. Hb >8.5 g/dL
7. White blood cell (WBC) >3.5 x 10^9/L
8. Platelets >100 x 10^9/L
9. Serum glutamic-oxaloacetic transaminase (SGOT)/aspartate aminotransferase (AST) and alkaline phosphatatse levels must be within twice the upper limit of normal range

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Woman who are pregnant, nursing or planning pregnancy within one and a half years after screening
2. Use of any Investigational Medicinal Product (IMP) within one month prior to screening or within five half-lives of the IMP, whichever is longer
3. Use of a putative disease modifying drug within one month of screening

4. Treatment with any medication targeted at reducing tumour necrotising factor (TNF) within three months of screening
5. Previous administration of AIMSPRO®
6. History of known allergy to animal proteins
7. Serious infections in the last three months
8. Active Hepatitis B or C
9. Active tuberculosis
10. Opportunistic infections within the last six months
11. History or suggestive signs of lymphoproliferative disease
12. Known recent substance abuse
13. Poor tolerability of venesection or poor access
14. Presence of a transplanted organ (other than a corneal transplant of >3 months duration)
15. Immunosuppressive therapy within one month of screening
16. Malignancy within the past five years
17. Signs or symptoms of severe, progressive or uncontrolled renal, hepatic, haematologic, gastrointestinal, endocrine, pulmonary, cardiac or neurological disease
18. Myocardial infarction, uncontrolled cardiac failure, unstable angina or uncontrolled systemic hypotension or hypertension within the past three months
19. Screening values which deviate 20% or more from the limits of normal which are considered to be clinically significant by the investigator

Date of first enrolment
21/10/2008

Date of final enrolment
01/08/2011

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Centre for Rheumatology and Connective Tissue Diseases
London
United Kingdom
NW3 2QG

Sponsor information

Organisation
Daval International Ltd (UK)

ROR

https://ror.org/056p0fy66

Funder(s)

Funder type
Industry

Funder Name
Daval International Ltd (UK)

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	01/01/2014		Yes	No