

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	<input type="checkbox"/> Prospectively registered
Registration date 24/10/2008	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 27/09/2013	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Prof Christopher Denton

Contact details

Centre for Rheumatology and Connective Tissue Diseases

Royal Free Hospital

Pond Street

London

United Kingdom

NW3 2QG

+44 (0)20 7317 7544

niamhq@gmail.com

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

NCT00769028

Secondary identifying numbers

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).

Study design

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

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

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 measure

Modified Rodnan Skin Score at 0, 6 and 26 weeks.

Secondary outcome measures

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 Council (MRC) Sum Score

Overall study start date

21/10/2008

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 childbearing 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 10⁹/L
8. Platelets >100 x 10⁹/L
9. Serum glutamic-oxaloacetic transaminase (SGOT)/aspartate aminotransferase (AST) and alkaline phosphatase levels must be within twice the upper limit of normal range

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

20

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**

England

United Kingdom

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

Sponsor information

Organisation

Daval International Ltd (UK)

Sponsor details

4a Gildredge Street
Eastbourne
United Kingdom
BN21 4RL
+44 (0)845 130 3014
bryanyoul@gmail.com

Sponsor type

Industry

Website

<http://www.davalinternational.com>

ROR

<https://ror.org/056p0fy66>

Funder(s)

Funder type

Industry

Funder Name

Daval International Ltd (UK)

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	01/01/2014		Yes	No