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Prevention of vascular damage in scleroderma with angiotensin-converting enzyme inhibition

Submission date	Recruitment status	[_] Prospectively registered
05/02/2002	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
05/02/2002	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
25/11/2010	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

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
M0616

Study information

Scientific Title

Acronym
QUINS

Study objectives
The objective is to assess the efficacy and tolerability of the Angiotensin-Converting Enzyme (ACE) inhibitor, quinapril, in the management of peripheral vascular manifestations and in preventing progression of visceral organ involvement in patients who fall into the limited cutaneous subset of Systemic Sclerosis (SSc).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled 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
Scleroderma

Interventions
Patients will be randomised to quinapril (20 mg/day) or placebo. The dose will be increased by 20 mg every 2 weeks to a maximum dose of 80 mg/day. Treatment will be for 3 years.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Quinapril

Primary outcome measure
The rate of occurrence of new ischaemic digital ulcers.

Secondary outcome measures
1. Frequency and severity of Raynaud's phenomenon
2. Introduction of vasodilators
3. Use of measures such as IV Iloprost to treat ischaemic digital lesions
4. Progression of scleroderma skin score
5. Progression of pulmonary and renal disease
6. Occurrence of death, significant macrovascular complications such as stroke and myocardial infarction, and pulmonary hypertension
7. Laboratory measures of endothelial/microvascular injury including von Willebrand factor antigen level, urinary levels of N-Acetyl-Glucosaminidase (NAG) and microalbuminuria

Overall study start date
01/12/2000

Completion date
30/11/2006

Eligibility

Key inclusion criteria
1. Patients aged 18 years or over, and
1.1. Limited cutaneous Systemic Sclerosis (lcSSc) and Raynaud's phenomenon in which scleroderma is limited to the hands, forearms, face, lower legs and feet, or
1.2. Raynaud's phenomenon and a SSc-specific autoantibody such as anticentromere antibodies, anti-topoisomerase 1, anti-RNApolymerase antibodies, anti-ThRNP antibodies and anti-U3RNP antibodies

Participant type(s)
Patient

Age group
Not Specified

Lower age limit
18 Years

Sex
Not Specified

Target number of participants
Not provided at time of registration

Key exclusion criteria

1. Known allergy to or intolerance of ACE inhibitors
2. Women of childbearing age not using reliable contraception [for example, abstinence, oral or implanted contraception, sexual partner had non-reversed vasectomy, or intra-uterine device (IUD)]
3. History of angioneurotic oedema
4. Significant impairment of renal or hepatic function
5. Severe obstructive valvular heart disease
6. Any other condition that would prevent compliance with treatment or adequate assessment

Date of first enrolment
01/12/2000

Date of final enrolment
30/11/2006

Locations

Countries of recruitment
United Kingdom

Wales

Study participating centre
Gwynedd Rheumatology Service
Bangor
United Kingdom
LL57 2PW

Sponsor information

Organisation
Arthritis Research Campaign (ARC) (UK)

Sponsor details
Copeman House
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Sponsor type

Charity

Website
http://www.arc.org.uk

ROR
https://ror.org/02jkpm469

Funder(s)

Funder type
Charity

Funder Name
Arthritis Research Campaign (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?
Protocol article	protocol	01/09/2002		Yes	No
Results article	results	01/11/2007		Yes	No