

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

Submission date 05/02/2002	Recruitment status No longer recruiting	☐ Prospectively registered ☒ Protocol
Registration date 05/02/2002	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 25/11/2010	Condition category Musculoskeletal Diseases	☐ 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

Protocol serial number
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

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

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(s)

The rate of occurrence of new ischaemic digital ulcers.

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Not Specified

Lower age limit

18 Years

Sex

Not Specified

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)

ROR

<https://ror.org/02jkpm469>

Funder(s)

Funder type

Charity

Funder Name

Arthritis Research Campaign (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	01/11/2007		Yes	No
Protocol article	protocol	01/09/2002		Yes	No

