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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

**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

## Study design
Randomised controlled trial

## Primary study design
Interventional

## 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 |