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Clopidogrel in systemic sclerosis

Submission date	Recruitment status	[_] Prospectively registered
22/10/2014	Stopped	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
02/12/2014	Stopped	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
23/02/2018	Skin and Connective Tissue Diseases	[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Scleroderma is an uncommon autoimmune disease that results in the buildup of excess connective tissue (fibrosis), which found underneath the skin and surrounding internal organs. The degree and seriousness of the condition depends upon the type of scleroderma that the patient has. Systematic sclerosis (SSC) involves both skin and internal organs. Symptoms include thickening of the skin, the buildup of hard lumps of calcium under the skin (which can lead to infection and ulceration) and Raynaud's phenomenon, a circulation problem that causes fingers and toes to turn white in the cold. Organs affected can include the heart, esophagus (food pipe), kidneys and intestines. These can lead to, among other things, shortness of breath, high blood pressure and diarrhea. Treatment options are limited, at the moment, and the prognosis for patients with severe skin and organ involvement is poor; they typically have a 10 year survival rate of less than 40%. The cause of the disease is unknown, but it is believed that the activation of platelets (blood cells that causes clots when we bleed) and resulting production of a chemical called serotonin may lead to tissue fibrosis. A recent study has shown that stopping platelet aggregation (the first step in platelet activation) using a drug called clopidogrel (an antiplatelet) leads to a reduction in fibrosis in laboratory mice. Here, we want to see if clopidogrel can help people with SSC, by reducing the amount of serotonin produced and therefore, fibrosis.

Who can participate?
Patients over 18 that have been diagnosed with scleroderma.

What does the study involve?
First of all, all participants undergo an extensive laboratory and clinical assessment which includes a review of their medical history, basic blood and urine laboratory tests, tests to check how well their lungs and heart are working and overall assessment of severity of disease. They are then given 75mg of clopidogrel, once a day for 12 months. During this time, the participants are given further clinical assessments and blood tests every three months to see how their disease is progressing.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
University Hospital of Patras (Greece)

When is the study starting and how long is it expected to run for?
December 2913 to December 2014

Who is funding the study?
University of Patras (Greece)

Who is the main contact?
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Clopidogrel in systemic sclerosis: an open labelled, proof of concept study

Acronym
N/A

Study objectives

The aim of this proof of concept, open label study is to assess whether clopidogrel, a strong inhibitor of platelet activation, can favorably affect fibrosis in patients with systemic sclerosis potentially by reducing the production of serotonin, a pivotal mediator of fibrosis.

Ethics approval required
Old ethics approval format

Ethics approval(s)
University Hospital of Patras Ethics Committee, 19/10/2013, ref. 8524

Study design
Single-center open-label uncontrolled proof-of-concept study

Primary study design
Interventional

Secondary study design
Non randomised study

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
Systemic Sclerosis/Rheumatology

Interventions
Treatment with Clopidogrel 75mg PO daily for 1 year

Intervention Type
Drug

Phase
Not Applicable

Primary outcome measure
Patients will be assessed after 1 year of treatment.
1. Improvement of FVC and/or DLco more than 10%
2. Improvement of MRSS skin score more than 20%

Secondary outcome measures
1. Improvement of laboratory endothelial markers(s-VCAM & s-ICAM)
2. Reduction in serotonin levels in platelet poor plasma

Overall study start date
05/12/2013

Completion date
05/12/2014

Reason abandoned (if study stopped)
Objectives no longer viable

Eligibility

Key inclusion criteria
1. Scleroderma diagnosis based on 2012 ACR/EULAR classification criteria
2. Age over 18

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
20

Key exclusion criteria
1. History of endocranial bleeding
2. History of gastrointestinal ulcer
3. Renal failure,EGFR less than 30ml/min based on MDRD formula

Date of first enrolment
05/12/2013

Date of final enrolment
05/12/2014

Locations

Countries of recruitment
Greece

Study participating centre

University Hospital of Patras
Patras
Greece
26500

Sponsor information

Organisation
University of Patras Research Committee (ELKE)

Sponsor details
University of Patras Campus
Rion
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Sponsor type
University/education

Website
http://research.upatras.gr

ROR
https://ror.org/017wvtq80

Funder(s)

Funder type
University/education

Funder Name
University of Patras, Medical School Research Committee (Greece)

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	17/05/2016		Yes	No