







# Clopidogrel in systemic sclerosis

<b>Submission date</b> 22/10/2014	<b>Recruitment status</b> Stopped	 Retrospectively registered
<b>Registration date</b> 02/12/2014	<b>Overall study status</b> Stopped	 Protocol not yet added
<b>Last Edited</b> 23/02/2018	<b>Condition category</b> Skin and Connective Tissue Diseases	 SAP not yet added
		 Results added
		 Raw data not expected as study has stopped
		 Study stopped

## Plain English Summary

### 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. Systemic 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?  
Dr Dimitris Daoussis  
jimdaoussis@hotmail.com

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr Dimitris Daoussis

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Protocol/serial number**  
N/A

## Study information

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

**Acronym**  
N/A

**Study hypothesis**

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

**Condition**

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

**Overall study end date**

05/12/2014

**Reason abandoned (if study stopped)**

Objectives no longer viable

## Eligibility

**Participant 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

**Participant exclusion criteria**

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

**Recruitment start date**

05/12/2013

**Recruitment end date**

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  
Patras  
Greece  
26500  
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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?
<a href="#">Results article</a>	results	17/05/2016		Yes	No