# Resveratrol as potential aortic growth inhibitor in patients with Marfan Syndrome

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|---|---|
| **Ethical review** | Approved WMO |
| **Status** | Recruiting |
| **Health condition type** | Congenital cardiac disorders |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON49268

**Source**
ToetsingOnline

**Brief title**
RESVcue Marfan

### Condition

- Congenital cardiac disorders
- Cardiac and vascular disorders congenital

**Synonym**
connective tissue disease, Marfan syndrome

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Academisch Medisch Centrum
**Source(s) of monetary or material Support:** Privé donatie

## Intervention

**Keyword:** Aortic growth inhibitor, Marfan Syndrome, Resveratrol

## Outcome measures

### Primary outcome

There are three main study parameters/endpoints:

1. A decrease in aortic aneurysm expansion rate in > 90% of the study subjects as measured by echo between baseline (at timepoint of inclusion in the study) and after twelve months of follow-up (after resveratrol treatment).

2. Any statistical significant beneficial change in aortic elasticity or aortic wall shear rate as measured by magnetic resonance imaging (MRI) between baseline (at timepoint of inclusion in the study) and after twelve months of follow-up (after resveratrol treatment).

3. Any statistical significant beneficial change in endothelial function as measured by Flow Mediated Dilatation (FMD)

### Secondary outcome

1. To evaluate functional cardiac parameters by echocardiography in Marfan patients upon treatment with resveratrol.

2. To evaluate changes in blood pressure/heart rate in patients with Marfan syndrome treated with resveratrol.

3. To evaluate changes in endothelial cell function in patients with Marfan syndrome treated with resveratrol by flow mediated dilation measurement (FMD).

4. To evaluate differences between Marfan patients who have had aortic replacement and Marfan patients with a native aorta, before or after resveratrol.

5. To evaluate differences between Marfan patients who have a haploinsufficient (HI) FBN1 mutation or a dominant negative (DN) FBN1 mutation. Geneticists determine the HI or DN status, however, skin cultures may provide conclusive results when the mutation effect is unpredictable.

# Study description

### Background summary

We have shown that the food supplement Resveratrol inhibits aortic growth and promotes aortic repair in Marfan Syndrome mice (doi: 10.1161/ATVBAHA.116.307841). The hypothesis is that Resveratrol treatment will also be protective against aortic dilatation and functional deterioration in humans with Marfan syndrome.

### Study objective

The aim of the study is to obtain sufficient data on beneficial effects of Resveratrol on aortic aneurysm expansion rate and functional properties in patients with Marfan syndrome to justify a phase IIb or a phase III randomized trial.

### Study design

A pre-post observational design with evaluation of cardiovascular parameters (primary and secondary outcomes) before and after 12 months of resveratrol treatment.

### Intervention

Resveratrol 500 mg/day for one year

### Study burden and risks

Study subjects will be evaluated before and after 1 year of Resveratrol treatment (2x) with various measurements. They will undergo echo, MRI, FMD, blood sampling and skin biopsy. Furthermore, patients will complete a Well-being questionnaire before and after 1 year of treatment.

# Contacts

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# Trial sites

## Listed location countries

Netherlands

# Eligibility criteria

**Age**
Adults (18-64 years)
Elderly (65 years and older)

## Inclusion criteria

- Marfan patients with a known FBN1 mutation
- Between 18-50 years of age
- Native aortic root (n<=50) or aortic root replacement (n<=50)
- At least 2 echocardiography measurements and 1 MRI scan of the aorta prior to the study
- Sinus rythm

## Exclusion criteria

- More than one vascular prosthesis
- Aortic root diameter > 45 mm

- Aortic surgery likely within 6 months of inclusion
- Aortic surgery in the last 6 months prior to inclusion
- Aortic dissection
- Contraindications for MR imaging
- Mental retardation

# Study design

## Design

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| Study phase: | 2 |
| Study type: | Interventional |
| Masking: | Open (masking not used) |
| Control: | Uncontrolled |
| Primary purpose: | Treatment |

## Recruitment

NL

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|---|---|
| Recruitment status: | Recruiting |
| Start date (anticipated): | 10-12-2018 |
| Enrollment: | 100 |
| Type: | Actual |

# Ethics review

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| Approved WMO Date: | 24-09-2018 |
| Application type: | First submission |
| Review commission: | METC Amsterdam UMC |
| Approved WMO Date: | 08-10-2018 |
| Application type: | Amendment |
| Review commission: | METC Amsterdam UMC |
| Approved WMO Date: | 19-11-2018 |

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|---|---|
| Application type: | Amendment |
| Review commission: | METC Amsterdam UMC |
| Approved WMO Date: | 13-02-2019 |
| Application type: | Amendment |
| Review commission: | METC Amsterdam UMC |
| Approved WMO Date: | 09-04-2019 |
| Application type: | Amendment |
| Review commission: | METC Amsterdam UMC |
| Approved WMO Date: | 18-11-2019 |
| Application type: | Amendment |
| Review commission: | METC Amsterdam UMC |

# Study registrations

## Followed up by the following (possibly more current) registration

No registrations found.

## Other (possibly less up-to-date) registrations in this register

No registrations found.

## In other registers

| Register | ID |
|---|---|
| CCMO | NL66127.018.18 |