

Treatment of cardiac amyloid light-chain amyloidosis with the green tea compound epigallocatechin-3-gallate

Submission date 29/09/2012	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
Registration date 05/10/2012	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 30/11/2016	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Systemic amyloid light-chain amyloidosis is a rare but serious condition where abnormal bone marrow cells produce excessive amounts of abnormal proteins, which form deposits called amyloid in tissues and organs throughout the body. Amyloid deposited in the heart can cause it to become enlarged and impair its ability to pump blood efficiently around the body, which may result in heart failure. Treatment currently involves having chemotherapy to damage the abnormal bone marrow cells and stop the production of the abnormal proteins. Epigallocatechin-3-gallate (EGCG), a chemical found in green tea, may be able to reduce the formation of amyloid and break it down. The aim of this study is to find out whether EGCG is able to reduce amyloid deposition in the heart.

Who can participate?

Patients with systemic amyloid light-chain amyloidosis affecting the heart

What does the study involve?

Participants are randomly allocated to take either increasing doses of EGCG capsules or a placebo (dummy drug) for 12 months. Participants come to the center for tests every 3 months. Echocardiography (a heart scan) is performed every 6 months. A heart MRI scan is carried out at the beginning and at the end of treatment.

What are the possible benefits and risks of participating?

EGCG may help to break down amyloid in the heart. There are no known risks of EGCG treatment.

Where is the study run from?

Ruprecht-Karls-University of Heidelberg (Germany)

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

December 2012 to November 2017

Who is funding the study?
Federal Ministry of Education and Research (Germany)

Who is the main contact?
Dr Stefan Schönland
stefan.schoenland@med.uni-heidelberg.de

Contact information

Type(s)
Scientific

Contact name
Dr Stefan Schönland

Contact details
Medical Department V
(Hematology/Amyloidosis Clinic)
Im Neuenheimer Feld 672
Heidelberg
Germany
D-69120
-
stefan.schoenland@med.uni-heidelberg.de

Additional identifiers

Clinical Trials Information System (CTIS)
2012-004520-38

Study information

Scientific Title
A randomised trial for the Treatment of cardiac AMyloid light-chain amyloidosis with the green tea compound Epigallocatechin-3-gAllate (TAME-AL)

Acronym
TAME-AL

Study objectives
One year treatment with Epigallocatechin-3-gallate (EGCG) reduces cardiac mass in patients with AL amyloidosis.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of The University Heidelberg, 08/04/2013, ref: AFmo-008/2013

Study design

Randomised placebo-controlled double-blind single-centre phase IIb study

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Amyloid light-chain amyloidosis

Interventions

EGCG capsules 400-1200 mg in increasing dosages or placebo for 1 year

Intervention Type

Drug

Phase

Phase II

Drug/device/biological/vaccine name(s)

Epigallocatechin-3-gallate

Primary outcome(s)

Left ventricular mass, measured by cardiac MRI

Key secondary outcome(s)

1. Quality of life, measured using the EORTC-QLQ-C30
 2. Left ventricle (LV) end diastolic and end systolic volumes with resulting ejection fraction, measured by cardiac MRI
 3. Cardiac function parameters (calculated left ventricular mass, Tissue DI, TAPSE, MAPSE)
 4. Cardiac biomarkers (cardiac troponin T hsTNT, NTproBNP)
 5. 6-minute walk distance
 6. Organ response in other affected organs, Gertz et al., 2005; standard criteria
 7. Improvement of hematological remission
 8. Overall survival
 9. Correlation of epigallocatechin gallate (EGCG) serum levels with organ response
 10. Number of adverse events according to Common Toxicity Criteria (CTC) version 4.0
- Measured 12 months after the start of treatment

Completion date

10/11/2017

Eligibility**Key inclusion criteria**

1. Biopsy proven systemic AL amyloidosis
2. Cardiac involvement with septum thickness >12 mm (without other causes as published by Gertz et al)

3. Hypertension or other potential causes of left ventricular hypertrophy
4. Previously treated with chemotherapy
5. Induced at least a very good partial remission of the underlying monoclonal plasma cell or B cell disorder

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. Age < 18 years
2. Concomitant multiple myeloma stage II and III (Salmon and Durie)
3. Concurrent chemotherapy necessary
4. Time to last chemotherapy > 6 months
5. Chronic liver disease
6. Bilirubin > 1,5 mg/dl
7. Not able to visit Amyloidosis Clinic in Heidelberg every 3 months

Date of first enrolment

01/12/2012

Date of final enrolment

01/10/2016

Locations**Countries of recruitment**

Germany

Study participating centre

Medical Department V

Heidelberg

Germany

D-69120

Sponsor information

Organisation

Ruprecht-Karls-University of Heidelberg (Germany)

ROR

<https://ror.org/038t36y30>

Funder(s)**Funder type**

Government

Funder Name

Bundesministerium für Bildung und Forschung FKZ: 01GM1107A

Alternative Name(s)

Federal Ministry of Research, Technology and Space, Bundesministerium für Bildung und Forschung, Federal Ministry of Education and Research, BMBF

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Germany

Results and Publications**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration