ISRCTN68399350 https://doi.org/10.1186/ISRCTN68399350

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

Submission date
29/09/2012

Recruitment status
No longer recruiting

Registration date
05/10/2012

Overall study status
Completed

Last Edited
30/11/2016

Condition category
Nutritional, Metabolic, Endocrine

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] 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 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?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
2012-004520-38

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

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 measure
Left ventricular mass, measured by cardiac MRI

Secondary outcome measures
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

Overall study start date
01/12/2012

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

Age group
Adult

Sex
Both

Target number of participants
38

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
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Sponsor information

Organisation
Ruprecht-Karls-University of Heidelberg (Germany)

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Sponsor type
University/education

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 Education and Research, BMBF

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Germany

Results and Publications

Publication and dissemination plan
To be confirmed at a later date

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration