

Implementing elements of the Chronic Care Model (CCM) in the care for neovascular age-related macular degeneration (wet AMD): Is it superior to usual care?

Submission date 04/02/2011	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 17/03/2011	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 17/11/2015	Condition category Eye Diseases	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Study website

[http:// www.hausarztmedizin.uzh.ch](http://www.hausarztmedizin.uzh.ch)

Contact information

Type(s)

Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

The chronic care for age-related macular degeneration study (CHARMED): A randomised controlled trial

Acronym

CHARMED

Study objectives

The implementation of core elements of the chronic care model (patient empowerment, delivering evidence based information, clinical information system, reminder system with structured follow up and frequent monitoring) results in better visual acuity (VA) in patients suffering from AMD, an increased disease specific quality of life (outcomes), mediated by a better treatment adherence.

Ethics approval required

Old ethics approval format

Ethics approval(s)

The ethics board of the Kanton Zurich (Kantonale Ethik-Kommission Zürich) approved on 17.12.2010 (KEK-ZH-NR: 2010-04391/1)

Study design

Multicentre randomised controlled trial

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 below to request a patient information sheet

Health condition(s) or problem(s) studied

Age-related macular degeneration (wet AMD)

Interventions

Intervention on the centres:

In each centre, a Chronic Care Coach (CCC) will provide care for intervention group patients according to the CCM. The CCC will be trained (in half-day workshops) for these tasks: Monitoring and organising the treatment, structuring and planning the monthly contacts for injections between patients and physicians including telephone contact with patients, patient instruction on self-management tasks (self-measurement of the visual function by Amsler-test and the Health Management Tool (HMT, assessed by iPhone), using of an action plan and organising of peer-group meetings in collaboration with Retina Suisse. Furthermore, at least two outreach visits will be performed in each centre, the first briefly after study onset and the second during the study year, to assess if the ETDRS will be conducted in a standardised way and to reveal possible problems which might have occurred.

Intervention on the patients:

1. Initially, patients will be individually taught by the chronic care coach about the study, evidence-based information about the disease, the symptoms, how to handle the HMT
2. Patients will be instructed to measure the visual acuity of both eyes weekly (with the Amsler-test and the HMT).
3. Patients will receive an action plan, which will tell them how to deal with the disease, to estimate the severity of symptoms for subsequent needed actions and how to react if they recognise any changes in the visual acuity. It also contains a checklist for the antibiotic eye drops and all important contact addresses.
4. Peer group meetings with experienced patients suffering from AMD will take place at least twice in collaboration with Retina Suisse.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

1. Visual acuity (VA)- Taken under standardised condition with the Early Treatment Diabetic Retinopathy Study (ETDRS) charts with a distance of 4 meters

Secondary outcome measures

1. Disease specific quality of life
 - 1.1. National Eye Institute Visual Function Questionnaire-25 (NEI VFQ-25)
2. Physiological outcome
 - 2.1. Central retinal thickness (assessed by the optical coherence tomography (OCT)
3. Health care utilisation
 - 3.1. Hospitalisation, emergency consultation differenced by consultations according to AMD and consultations according to other health reasons
4. Accordance to the Chronic Care Model
 - 4.1. Assessment of chronic illness care (ACIC)
 - 4.2. Patient Assessment of Chronic Illness Care (PACIC)

Overall study start date

01/03/2011

Completion date

31/12/2012

Eligibility

Key inclusion criteria

1. Male or female patients with neovascular age-related macular degeneration (wet AMD)
2. Eligible for a therapy with anti-angiogenic drug
3. Visual acuity less than equal to 0.05 (assessed by Early Treatment Diabetic Retinopathy Study ETDRS charts)
4. Age more than 50 years
5. Written informed consent given before any study related procedure is performed

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

A total sample size of 352 patients is needed (including the drop out rate of 25%). Around 14 specialised medical doctors from leading AMD centres in Switzerland which include around 25 patients each

Key exclusion criteria

1. Serious general or psychological illness (advanced malignant tumours, serious depressive episodes, evidence of dementia)
2. Insufficient language skills (informed consent, patient information and questionnaires will be provided in German and French)
3. Patients with any invasive medical treatment for wet AMD in the past

Date of first enrolment

01/03/2011

Date of final enrolment

31/12/2012

Locations

Countries of recruitment

Switzerland

Study participating centre

Institut fuer Hausarztmedizin der Universitaet Zurich
Zurich

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Sponsor information

Organisation

University Hospital Zurich (Universitaetsspital Zurich) (Switzerland)

Sponsor details

Institute for Family Medicine of the University of Zurich (Institut fuer Hausarztmedizin der Universitaet Zurich)

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Sponsor type

Government

Website

[http:// www.hausarztmedizin.uzh.ch](http://www.hausarztmedizin.uzh.ch)

ROR

<https://ror.org/01462r250>

Funder(s)

Funder type

Government

Funder Name

Institute for Family Medicine of the University of Zurich (Institut fuer Hausarztmedizin der Universitaet Zurich) (Switzerland)

Funder Name

Future doctor / Zuerrcher Foundation for the promotion of family medicine (Zukunft Hausarzt / Zuerrcher Stiftung zur Foerderung der Hausarztmedizin) (Switzerland)

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?
Protocol article	protocol	11/10/2011		Yes	No
Results article	results	16/11/2015		Yes	No