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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

Registration date
17/03/2011

Overall study status
Completed

Last Edited
17/11/2015

Condition category
Eye Diseases

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Study type(s)
Treatment

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

Key secondary outcome(s))
1.Disease specific quality of life
1.1. National Eye Institute Visual Function Questionnare-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)

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

Healthy volunteers allowed
No

Age group
Adult

Sex
All

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
Switzerland
8091

Sponsor information

Organisation
University Hospital Zurich (Universitaetsspital Zurich) (Switzerland)

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

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?
Results article	results	16/11/2015		Yes	No
Protocol article	protocol	11/10/2011		Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes