

Improving medication safety for patients with chronic renal impairment in general practice

Submission date
29/03/2007

Recruitment status
No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date
30/05/2007

Overall study status
Completed

☐ Statistical analysis plan

☒ Results

Last Edited
23/05/2013

Condition category
Urological and Genital Diseases

☐ 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
01GK0302

Study information

Scientific Title

Acronym

TP 1

Study objectives

In comparison with the control group, the intervention will result in a higher proportion of correctly adjusted drugs in patients with chronic renal impairment.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved by Ethics Committee of Johann Wolfgang Goethe University on the 18th September 2006.

Study design

Cluster-randomised controlled trial; we randomised 23 General Practitioner (GP) practices in the intervention and 23 practices in the control group.

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

GP practice

Study type(s)

Quality of life

Participant information sheet

Health condition(s) or problem(s) studied

Chronic renal impairment (grade III or higher)

Interventions

Each participating practice attended one of four consecutive introductory meetings and was randomised to the intervention or control group. The practices are told to recruit ten suitable patients during a period of four weeks after the meeting. The date on which the data sheets for these ten patients arrive at our institute (= T0) will be registered as the start of the six-month follow-up period. Six months later, each practice will be asked to provide data sheets for the same patients (= T1).

Intervention:

Introduction of an electronic support system for dose adjustment of drugs (software DOSING)

plus information package about chronic renal impairment for doctors and patients for six months.

Control:
Care as usual.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Number of medications which have not been correctly adjusted to patient's renal function, measured at baseline (T0) and again after six months (T1).

Secondary outcome measures

1. Number of patients in risk group with recently measured creatinine, measured at baseline (T0) and again after six months (T1)
2. Assessment of feasibility and usefulness of the tested electronic support system by participating General Practices (GP's), measured at baseline (T0) and again after six months (T1)

Overall study start date

21/02/2007

Completion date

13/02/2008

Eligibility

Key inclusion criteria

Patient level:

1. Patients with established chronic renal impairment grade III or higher (creatinine clearance below 50 ml/min)
2. Patients at risk of developing chronic renal impairment (70 years or older with hypertension = risk group)

Practice level:

1. Use of computer during consultation
2. Use of computer for prescribing medications

Participant type(s)

Patient

Age group

Not Specified

Sex

Not Specified

Target number of participants

400 patients

Key exclusion criteria

Patient level:

1. Terminally ill patients
2. Patients with dialysis treatment

Practice level:

Routine use of an electronic support system for dose adaption in patients with chronic renal impairment.

Date of first enrolment

21/02/2007

Date of final enrolment

13/02/2008

Locations**Countries of recruitment**

Germany

Study participating centre

Institute for General Practice

Frankfurt

Germany

D-60590

Sponsor information**Organisation**

German Federal Ministry of Education and Research (Bundesministerium Für Bildung und Forschung [BMBF]) (Germany)

Sponsor details

Hannoversche Strasse 28-30

Berlin

Germany

10115

Sponsor type

Government

Website

<http://www.bmbf.de/en/index.php>

ROR

<https://ror.org/04pz7b180>

Funder(s)

Funder type

Government

Funder Name

German Federal Ministry of Education and Research (Bundesministerium Für Bildung und Forschung [BMBF]) (Germany) (ref: 01GK0302) - notification of February 7, 2006

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?
Results article	results	06/09/2012		Yes	No