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

Submission date
29/03/2007

Recruitment status
No longer recruiting

Registration date
30/05/2007

Overall study status
Completed

Last Edited
23/05/2013

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[_] 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
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

Study type(s)
Quality of life

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

Key secondary outcome(s))
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)

Completion date
13/02/2008

Eligibility

Key inclusion criteria
Patient level:
1. Patients with established chronic renal impaiment 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

Healthy volunteers allowed
No

Age group
Not Specified

Sex
Not Specified

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)

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

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				

Results article	06/09/2012	Yes	No