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Reduction of inappropriate medication and adverse drug events in older patients

Submission date
11/09/2013

Recruitment status
No longer recruiting

Registration date
30/09/2013

Overall study status
Completed

Last Edited
21/07/2021

Condition category
Injury, Occupational Diseases, Poisoning

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

Plain English summary of protocol

Background and study aims
In the treatment of patients with long-term illness, treatment with many drugs (polypharmacy) is common. Polypharmacy in elderly patients is often associated with an inadequate use of drugs, which leads to more drug-drug interactions, adverse drug events, hospital admissions and rising costs for the health system. A big part of the drugs in polypharmacy is prescribed without demonstrated benefit for the patient. In this study we want to show that the reduction of drugs especially in elderly patients leads to a reduction of mortality (death), hospital admissions, falls and fractures and to a better mental functioning and quality of life of patients.

Who can participate?
People aged 74 or older with a drug therapy of eight drugs or more.

What does the study involve?
General practitioners (GPs) will be randomly allocated to one of two groups. GPs from one group will provide standard care to their patients. GPs from the other group will check the therapies of their patients in consultation with a panel of expert's which will check the drugs regarding appropriateness, possible dangerous side effects, medical indication and age of the patients. Together, they will select drugs which can be discontinued. The GP will have the last decision on discontinuation of a drug - in consultation with the patient. At the beginning and at the end of the study several tests will be carried out and results will be compared. Also, for assessing the quality of life, the cognitive (mental) function and the mental wellbeing of the patients, interviews will be carried out at the beginning and at the end of the study.

What are the possible benefits and risks of participating?
There may be a benefit for the patients taking part in terms of a thorough check of their drug therapy and eventually a reduction of the number of drugs to be taken. Consequently, there may be a reduction of side effects and undesired interactions between two or more drugs. The risk with discontinuation of drugs is that the disease or the overall health status depending on the underlying diseases will get worse. Therefore, patients will be checked and followed very carefully by their GP. And, within the study, discontinued drugs can be reintroduced in the therapy at any time.

Where is the study run from?
South Tyrolean Academy of General Practice, Bolzano, Italy

When is the study starting and how long is it expected to run for?
December 2012 to November 2015

Who is funding the study?
The Italian Ministry of Health and Council of Health Service of the Autonomous Province of Bolzano South Tyrol

Who is the main contact?
1. Prof. Christian Wiedermann (christian.wiedermann@asbz.it)
2. Dr Giuliano Piccoliori

Contact information

Type(s)
Scientific

Contact name
Dr Giuliano Piccoliori

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39047

Additional identifiers

Protocol serial number
RF-2010-2319605

Study information

Scientific Title
Polypharmacy - Reduction of Inappropriate Medication and Adverse drug events in older patients: a randomized controlled trial

Acronym
PRIMA

Study objectives
1. The evaluation of polypharmacy according to established criteria will lead to reduced polypharmacy, potential adverse drug interactions, hospital admissions and referrals to emergency departments.
2. The reduction of polypharmacy will be accompanied by an improvement of quality of life, mental functioning and mental wellness.

Ethics approval required

Old ethics approval format

Ethics approval(s)
Ethics committee of Bolzano, 15/05/2013, ref: 42-2013

Study design
Cluster randomized controlled trial

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Reduction of polypharmacy in elderly patients

Interventions
A cluster-randomized controlled trial aiming at the outcome after reduction and/or discontinuation of inappropriate medication in older patients. In the proposed trial, the physicians will be randomized with a computer tool (cluster) to receive or not receive advice from the experts board.

Intervention group:
1. Recommendation for discontinuation of drugs by a panel of experts in consultation with the general practitioner
2. Discontinuation of drugs with no evidence for benefit or even negative riskbenefit balance according to the Garfinkel Algorithm, the EbM guidelines and UpToDate software, PRISCUS list, STOPP Criteria and the drug interaction database.

Control: physicians of the control group will record and document their patients the same way (CRF Form), but won't get advice on the drug therapy from the experts board.

Both groups, intervention and control, will have to record / document consecutively any events of death, falls, adverse drug events (ADEs) and bone fractures.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Hazard ratio for the composite endpoint of first hospital admission and death measured by the number of deaths in the study population at 24 months

Key secondary outcome(s))
1. Mortality, measured by the number of deaths (the numerator of the mortality rate) in patients of the two study groups (the population denominator of the mortality rate), respectively, at the time point 24 months after study enrolment
2. Hospital admission, measured as number of admissions to local hospitals and length of

hospital stays measured in days as recorded in a single database within a time period of 24 months after study enrolment
3. Adverse drug events, measured as number of severe adverse events documented in patients charts of the general practitioner or in hospital discharge letters in patients of the two study groups, respectively, at the time point 24 months after study enrolment
4. Falls, measured as number of events which result in a person coming to rest inadvertently on the ground or floor or other lower level as documented in patient charts of the general practitioner and of the hospital in patients of the two study groups, respectively, during the period of 24 months after study enrolment
5. Fractures, measured as number of bone fractures documented radiographically in charts of patients of the two study groups, respectively, during the period of 24 months after study enrolment
6. Health expenditure, measured as estimated sum of the expenditure due drugs and hospital admissions in patients of the two study groups, respectively, at the time point 24 months after study enrolment
7. Improvement of the cognitive function assessed by the Mini Mental Status
8. Quality of life, measured by the SF12
9. Mental wellness, assessed by the Geriatric Depression Scale

Completion date
01/12/2016

Eligibility

Key inclusion criteria
1. Aged over 74 years
2. Taking eight or more drugs

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Senior

Sex
All

Total final enrolment
622

Key exclusion criteria
1. Life expectancy assumed to be less than three months
2. Advanced cancer
3. Ongoing chemotherapy and/or therapeutic radiation
4. Severe dementia
5. Patients not able to give informed consent

Date of first enrolment
01/12/2012

Date of final enrolment
30/11/2015

Locations

Countries of recruitment
Italy

Study participating centre
via del Comune 39
S. Cristina
Italy
39047

Sponsor information

Organisation
Council of Health Service of the Autonomous Province of Bolzano South Tyrol (Italy)

Funder(s)

Funder type
Government

Funder Name
Ministero della Salute

Alternative Name(s)
Italian Ministry of Health, Italy Ministry of Health, Ministry of Health of Italy, Ministry of Health - Italy, Ministry of Health, Italy

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Italy

Funder Name
Council of Health Service of the Autonomous Province of Bolzano South Tyrol (Italy)

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Dr. Piccoliori Giuiano, drgiupic@tin.it, in SPSS format starting from 01/06/2018 for 10 years. Data will be made available only for scientific purposes and analyses, individual participant data will be pseudonymized.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		20/03/2021	22/03/2021	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes