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Assessment of the Italian Medicines Use Review for asthma

Submission date	Recruitment status	[_] Prospectively registered
05/01/2015	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
14/01/2015	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
26/04/2017	Respiratory	

Plain English summary of protocol

Background and study aims
Cognitive pharmaceutical services are defined as the use of specialised knowledge by pharmacists for the promotion of effective and safe use of drugs by patients. I-MUR is the first cognitive pharmaceutical service tested and introduced in Italy. The aim of this study is to assess the clinical and economic effects of I-MUR interventions provided by Italian community pharmacists to patients with asthma. The RE I-MUR study is the third phase of a research and development project. Phase one was done between October 2012 and January 2013 to assess the feasibility of community pharmacists delivering I-MUR, which was new for Italy. Phase two was done between October 2013 and November 2013 to obtain feedback from patients and general practitioners.

Who can participate?
Patients with asthma, aged at least 18

What does the study involve?
Pharmacists are allocated to one of two groups.
Group A pharmacists will deliver I-MUR to patients at the beginning of the study and group B pharmacists will deliver the intervention at 3 months during private consultations. Patients, once enrolled in the study, will meet their pharmacists four times (every 3 months) during 9 months. During each meeting, pharmacists will invite patients to complete the Asthma Control Test, identify the number of medicines used by patients and assess patients' adherence to treatment.

What are the possible benefits and risks of participating?
There will be no risks for the patients. Patients receiving the I-MUR service will be at no greater risk than patients receiving usual clinical care.

Where is the study run from?
Ten centres covering 15 Italian regions from the north to the south of Italy: Trentino Alto Adige, Lombardia, Sicilia, Puglia, Sardegna, Piemonte, Valle d'Aosta, Veneto, Friuli Venezia Giulia, Toscana, Emilia, Marche, Abruzzo, Lazio and Campania.

When is the study starting and how long is it expected to run for?
September 2014 to June 2015

Who is funding the study?
Italian Pharmacists' Federations (Federazione Ordini Farmacisti Italiani)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
0281314

Study information

Scientific Title
Randomised Evaluation of the Italian Medicines Use Review provided by community pharmacists using asthma as a model

Acronym
RE I-MUR

Study objectives

Null hypothesis: the I-MUR service (aimed at optimising the number of medicines used by patients, identifying the number of pharmaceutical care issues and improving patients' adherence to asthma medications) provided by community pharmacists does not affect the severity of asthma, as measured with the Asthma Control Test score.
Alternative hypothesis: I-MUR has an impact on the severity of asthma.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Faculty of Science Ethics Committee of the University of Kent (UK) (Faculty of Sciences Research Ethics Advisory Group for Human Participants on 18 February 2014 with reference number 0281314
2. Ethics Committee of Spedali Civili di Brescia (Lombardia regions), which is the reference centre for all Italian participating regions, on 3 June 2014 with reference number NP 1710

Study design
Cluster-randomised controlled trial, with each pharmacist representing a cluster. Community pharmacists, stratified by the region of Italy, will be randomly assigned to one of two groups (A and B).

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Community

Study type(s)
Other

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Asthma

Interventions
The I-MUR intervention covers patients' demographics, their regular medications including those used for asthma, patients' attitudes towards their medications and adherence to treatments, pharmaceutical care issues identified by the pharmacists, pharmacists' advice given to patients including healthy living advice, pharmacists' advice given to doctors, pharmacists' own views on the potential benefit to the patient of the I-MUR service.

Community pharmacists, stratified by the region of Italy, will be randomly assigned to one of two groups (A or B). Each pharmacist will recruit five patients. Group A pharmacists will deliver I-MUR to patients at the beginning of the study and group B pharmacists will deliver the intervention at 3 months. Pharmacists will administer the Asthma Control Test before I-MUR and

at 6 months and 9 months in each group. Patients will be followed up at 3 months and 6 months. After each consultation, pharmacists will enter the results into a web-based template, maintaining the anonymity of patients.

Intervention Type
Other

Primary outcome measure
Severity of asthma, assessed with the Asthma Control Test score

Secondary outcome measures
1. Number of active ingredients used by patients, as reported by patients
2. Number of pharmaceutical care issues identified during provision of the I-MUR service
3. Patients' adherence to asthma medication during and after the I-MUR service provision, measured with questions embedded in the I-MUR instrument
4. Overall health-care costs, estimated on the basis of the severity of asthma, before, during and after provision of the I-MUR service

Overall study start date
01/09/2014

Completion date
30/06/2015

Eligibility

Key inclusion criteria
Pharmacies must have:
1. An area for private consultation with patients
2. Internet connection at the place of the consultation

Pharmacists must:
1. Be qualified and registered with the Italian Pharmacy Board practicing in Italy
2. Have at least 1 year of experience in providing advice to patients
3. Already provide one or more services such as blood pressure monitoring, smoking cessation, cholesterol monitoring, signposting and food intolerance testing to demonstrate advanced consultation skills and experience
4. Be able to attend training sessions

Patient selection will take place over the same defined period for all 360 pharmacists: before baseline. Patients will be identified by pharmacists from their medication history, from their prescriptions, or by referral from general practitioners, according to inclusion and exclusion criteria:
1. Age at least 18 years old
2. Diagnosed with asthma, for at least 6 months before enrolment to the study
3. Have at least one prescription for asthma medication with the Anatomical, Therapeutic Chemical Classification R03: drugs for obstructive airways disease

Participant type(s)
Mixed

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
360 community pharmacists and 1800 patients

Key exclusion criteria
Pharmacies do not have:
1. Internet access
2. Consultation room

Pharmacists:
1. Involved in any other clinical pharmacy research project

Patients:
1. Have terminal illness (an advanced stage of a disease with an unfavourable prognosis and no known cure) as identified by the pharmacists through the prescription coding
2. Are currently enrolled in another clinical trial
3. Do not self-administer their inhaler
4. Do not have the ability to communicate well in Italian (both verbally and in writing)

Date of first enrolment
01/09/2014

Date of final enrolment
31/10/2014

Locations

Countries of recruitment
Italy

Study participating centre
15 Italian regions
Italy
-

Sponsor information

Organisation
FOFI (Italian Pharmacists' Federation = Federazione Ordini Farmacisti Italiani)

Sponsor details
Via Palestro 75
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Sponsor type
Other

Website
http://www.fofi.it/

ROR
https://ror.org/02ztj7h33

Funder(s)

Funder type
Other

Funder Name
FOFI (Italian Pharmacists' Federation = Federazione Ordini Farmacisti Italiani)

Results and Publications

Publication and dissemination plan
To be confirmed at later date

Intention to publish date
01/01/2016

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	21/04/2015		Yes	No

Results article	results	24/04/2017	Yes	No