

# Assessment of the Italian Medicines Use Review for asthma

<b>Submission date</b> 05/01/2015	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 14/01/2015	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 26/04/2017	<b>Condition category</b> Respiratory	<input type="checkbox"/> Individual participant data

## 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?  
Andrea Manfrin  
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## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**Protocol serial number**  
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

## **Study type(s)**

Other

## **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(s)**

Severity of asthma, assessed with the Asthma Control Test score

## **Key secondary outcome(s)**

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

**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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**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

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## Sponsor information

**Organisation**

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

**ROR**

<https://ror.org/02ztj7h33>

## Funder(s)

**Funder type**

Other

**Funder Name**

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

# Results and Publications

## 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?
<a href="#">Results article</a>	results	24/04/2017		Yes	No
<a href="#">Protocol article</a>	protocol	21/04/2015		Yes	No