Supplementary file
INFORMATION SHEET AND CONSENT FORM FOR THE PATIENT

Impact of a PHARmacist-included MOBILE Geriatrics team intervention on potentially inappropriate drug prescribing

PharMoG
31/17/0353

Version No.2 dated 16/12/2019
Sponsor: CHU Toulouse
Principal Investigator: Philippe CESTAC PharmD, PhD

Dear Sir or Madam,

A pharmacist or geriatrician from the Toulouse CHU geriatrics team has invited you to participate in a research trial sponsored by the CHU of TOULOUSE. Before deciding, please take the time you need to carefully read this document. It will provide you with all the relevant information about the various aspects of this research. Please feel free to ask the pharmacist or geriatrician any questions you may have about what you have read.

The decision to participate in the trial is entirely yours. If you do not want to participate, you will continue to receive the best possible medical care based on today’s knowledge.

Why this research?

From 65 years of age, the number of chronic diseases increases and is a source of polypharmacy, that is to say the “administration of several drugs simultaneously or the administration of too many drugs”.

Elderly people are more sensitive to adverse drug reactions. According to studies, 5% to 25% of hospitalizations and 10% of emergency visits are due to adverse drug reactions. Each new prescription increases adverse events from 12% to 18% and the risk of hospitalization to 11%.

Also, the difficulties inherent in the packaging or the complexity of the treatment plan increase the risk of not taking the drugs and therefore therapeutic failures.

To reduce these risks, a collaboration between healthcare professionals is essential. Pharmacists, thanks to their knowledge about drugs and their proper use, can help optimise the impact of the treatments prescribed by your doctor.

To our knowledge, a study that evaluates the impact of a pharmacist-included mobile geriatrics team on potentially inappropriate drug prescribing has not been performed yet in France.

What is the objective of this research?

The main objective of the PharMoG study is to compare the average number of a patient’s potentially inappropriate drug prescriptions before the intervention of a mobile geriatric team that includes a pharmacist and after the intervention, when the patient is discharged from the hospital department in which they were admitted.

The secondary objectives will be to evaluate the impact of the pharmacist included mobile geriatric team 3 months after the intervention on potentially inappropriate prescriptions, polypharmacy, falls, and hospitalizations.

How will this research be conducted?

PHARMOG is a local, single-centre, prospective study. It will take place in all the departments of the CHU of TOULOUSE and will last 15 months. It is a descriptive study. It will not change your usual medical care, except that your prescriptions will be analysed and optimised. Your participation in the study will last 3 months. A total of 250 participants will be included.
**Who can participate?**

You can participate if:

- You are 75 years or older
- You are hospitalized at the Toulouse University Hospital in a medical, surgical, or emergency department, for which the mobile geriatric team was requested
- You have been prescribed at least five drugs before the intervention
- You gave your oral consent to participate in the study (or oral consent given by a representative: trusted person and/or a family member, if necessary)
- You are affiliated to a social security scheme or equivalent

You cannot participate if:

- You are less than 75 years old
- You had fewer than five prescription drugs before the intervention
- You are legally protected (under guardianship or prescription of the court)
- You are already participating in another research protocol

**What will be asked of you?**

During the first visit, called the inclusion visit, you will confirm that you agree to participate in the study in the presence of the investigator (pharmacist or geriatrician). The participation criteria will be checked, and you will be included as a participant if your eligibility is confirmed. Your agreement for participating in the study will be recorded in your medical record.

The pharmacist of the mobile geriatric team will ask you about how you take your medications, the difficulties you may have encountered, and the potential adverse drug reactions. The pharmacist will also ask for your community pharmacist’s contact information to collect information about your usual treatment. This inclusion visit will last about 30 minutes.

The second study visit will be a telephone call 3 months after your inclusion. We will collect information about your latest prescriptions and ask about possible falls, if you went to the emergency room or if you were hospitalized during these 3 last months. This call will last about 15 minutes.

Your participation in this study is entirely voluntary. You can end it any time and for any reason without consequences on your medical and pharmaceutical care.

You must be affiliated to a social security scheme or equivalent.

**What are the expected benefits?**

The expected benefits are a reduction in hospitalizations, the number of potentially inappropriate prescriptions, adverse drug reactions, and health insurance costs.

**What are the possible disadvantages?**

You will have to make yourself available for the 3-month follow-up phone call and answer the pharmacist’s questions. There are no known risks connected to the research procedures given that all the decisions will be based on validated (national or international) medical recommendations and these decisions will be taken with your doctors. The studied intervention will therefore not incur any additional risk.

**What are your rights?**

The doctor is required to give you all necessary explanations concerning this research. If you wish to withdraw your consent at any time and regardless of the reason, you will continue to receive the best medical care and your decision will not affect his or her future medical supervision.

In the framework of this biomedical research, your data will undergo computer processing to analyse the research results relative to the research objectives that you are hereby informed of. The body responsible for the data processing is the University Hospital (CHU) of Toulouse, represented by its legal representative in office.
The study physician and other study staff will gather information about you, your health, your prescriptions, and your participation in the study. This information, called "personal information", is recorded on forms, referred to as the case report forms, provided by the sponsor or, on secure online forms dedicated to the study. Only information needed for your treatment and the research aims will be collected; these data will be kept for 15 years after the study and archived. You will only be identified by a code and your initials. The code is used so that the study doctor can identify you if necessary. This data processing is based on Article 6 of the General Data Protection Regulation (GDPR), namely the execution of a public interest mission vested in the data controller and the legitimate interests pursued by it. In addition, under article 9 of the GDPR, the data controller may extraordinarily process specific categories of data, including health data, specifically for scientific research purposes.

In accordance with the provisions of the law relating to data processing, files and freedoms (French law No. 78-17 of January 6, 1978 relating to data processing, files and freedoms modified by law No. 2018-493 of 20 June 2018 on the protection of personal data) and the GDPR (EU Regulation 2016/679), you have the right to access and rectify your personal information. You may also request a restriction on the processing of your personal information, oppose certain types of processing of such personal information, or request that personal information be deleted. However, some previously collected data may not be deleted under Articles 17.3.c and 17.3.d. GDPR, if this deletion is likely to make it impossible or seriously jeopardize the achievement of the research objectives. You may also request that personal information about you be provided to you or a third party in a digital format (portability right).

You can exercise these rights by asking the study doctor in writing. The Sponsor will respond to your requests to the extent possible in accordance with its other legal and regulatory obligations and where required by law.

The data analysis may be carried out within your country, in other countries of the European Economic Area (EEA), in the United States and in countries outside the EEA.

The sponsor may disclose personal information to regulatory agencies or research partners in order to apply for marketing authorizations and reimbursement agreements. These individuals, companies and agencies may be in your country, in other countries of the EEA, in the United States and in countries outside the EEA. Some countries outside the EEA may not offer the same level of privacy protection as your country. The Sponsor will however maintain as much as possible the confidentiality of all the personal information received within the limits of the law.

The sponsor will adopt the appropriate contractual measures, including its Privacy Shield certification and standard data protection clauses, to ensure that relevant recipients outside the EEA provide an adequate level of protection for your personal information as set out in this form and in accordance with the law.

You also have the right to oppose the transmission of data covered by professional secrecy that may be used in the context of this research and to be processed. You can also access all your medical data in accordance with the provisions of Article L1111-7 of the French Public Health Code directly or through the doctor of your choice. These rights are exercised with the doctor who follows you during the research and who knows your identity. The competent authorities and the sponsor or its authorized representatives may also need access the medical records to verify the data collected as part of the study. Your coded personal information may be used for further scientific research with applicable laws and regulations.

If you have any other questions about the collection and use of your personal information or the rights associated with this information, please contact the Data Protection Officer of the University Hospital of Toulouse (DPO@chu-toulouse.fr) or the study doctor.

If, despite the measures put in place by the Sponsor, you believe that your rights are not respected, you can file a complaint with the data protection supervisory authority in your country of residence (the CNIL for France on the website https://www.cnil.fr/fr/donnees-personnelles/plaintes-en-ligne).

In accordance with French law No 2012-300 of 5 March 2012 relating to research involving human persons:
- This research has received a favourable opinion from the the South-West and Overseas Territories II Ethics Committee and authorization from the National Agency for the Safety of Medicines and Health Products (ANSM).
- The sponsor of this research – the CHU of Toulouse – has taken out civil liability insurance with Lloyd’s Insurance Company SA
- Persons who have suffered damage after participating in a research study may make a claim with the regional commissions for conciliation and compensation of medical accidents.
- Once this research is completed, if you wish to, you will be personally informed about the overall results by the study doctor as soon as they become available.

After reading this information sheet, do not hesitate to ask your doctor any questions you may have. After thinking about it, if you agree to participate in this research, you must complete and sign the consent form. A copy of the completed document will be provided to you.

**Contact information for the pharmacist or physician at the study site:**

Name and Surname: …………………………………………………………………………………………………..

Phone number: …………………………………………………………………………………………………..

Professional address: …………………………………………………………………………………………..

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*We thank you for taking time to read this document.*
Certification by the pharmacist or physician who obtained the patient consent to participate in the study:

*PharMoG*

31/17/0353

I, the undersigned, doctor: ........................................................................................................

pharmacist or physician investigator at the CHU of TOULOUSE certify to having obtained oral consent from Mr/Mrs (patient name)

................................................................................................................................. for his/her participation in the PHARMOG study on the (date of oral consent) ____/___/____.

A copy of the information letter and of this certification was given to the patient on ____/___/____.

Physician’s or Pharmacist’s signature / Date
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The decision to participate for the person you represent in the trial is entirely yours. If you do not want the person you represent to participate, he or she will continue to receive the best possible medical care based on today's knowledge.

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The data analysis may be carried out within your country, in other countries of the European Economic Area (EEA), in the United States and in countries outside the EEA.

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Phone number: ………………………………………………………………………………………………………………………..

Professional address: …………………………………………………………………………………………………………

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*We thank you for taking time to read this document.*
Certification by the pharmacist or physician who obtained the patient’s representative oral consent to participate in the study:

PharMoG

31/17/0353

I, the undersigned, doctor: ..............................................................

pharmacist or physician investigator at the CHU of TOULOUSE certify to having obtained oral consent from the legal representative (trusted person or relative) of Mr/Mrs (patient name) ..........................................................

........ for his/her participation in the PHARMOG study on the (date of oral consent) |__|__|__|__|__|

A copy of the information letter and of this certification was given to the patient’s legal representative on |__|__|__|__|__|__|.

Physician’s or Pharmacist’s signature / Date