Usefulness of white blood cell count in the diagnosis of infection: comparison between young and geriatric hospitalized groups.

20/02/2019

Title of the study:
Usefulness of white blood cell count in the diagnosis of infection: comparison between young and geriatric hospitalized groups.

Sponsor of the study:
VUB Brussels health campus, laarbeeklaan 103, 1090 Jette
UZ Brussels, laarbeeklaan 101, 1090 Jette

Medical Ethics Committee:
Central ethical commission of UZ Brussels

Local investigators:
Hanne Maes, student medecin, VUB
Prof. Nathalie Compté, geriatrics department UZ Brussels
Prof. Bert Bravenboer, geriatrics department UZ Brussels
Prof. Tony Mets, geriatrics department UZ Brussels

I Information vital to your decision to take part (3 pages)

Introduction

You are being invited to take part in an observational clinical study. This means that the treatment you have been offered was prescribed in the usual manner, in accordance with the conditions of good medical practice and independently of your possible participation in this study.
We are simply asking you whether we can collect data from your medical records to be able to combine them with those of other patients receiving the same treatment and to process them statistically for research purposes. No additional diagnostic or monitoring procedure will be proposed, apart from three blood analyses, one viral nose-throat swab, and a few questionnaires we will ask you to complete

Before you agree to take part in this study, we invite you to take note of its implications in terms of organisation, possible risks and benefits, to allow you to make a decision with full awareness of the implications. This is known as giving “informed consent”.

Please read these few pages of information carefully and ask any questions you want to the investigator or his/her representative.

There are 3 parts to this document: the information essential to your decision, your written consent and supplementary information (appendices) detailing certain aspects of the basic information.

If you take part in this study, you should be aware that:

- The treatment offered to you by the investigator in accordance with current recommendations will not be altered if you take part in the study.
- This clinical study is being conducted after having been reviewed by one or more ethics committees.
- Your participation is voluntary and must remain free from any coercion. It requires the signature of a document expressing your consent. Even after having signed this document, you can stop taking part by informing the investigator.
- The data collected on this occasion are confidential and your anonymity is guaranteed during publication of the results.

- Insurance has been taken out in case you should suffer any damage in connection with your participation in this clinical study.
- You may contact the investigator or a member of his/her team at any time should you need any additional information.

Further information about your “Rights as a participant in a clinical study” can be found in appendix 2.

Objectives and course of the study

Objectives: This clinical study has been organised with the aim of gaining a better understanding of the changed functioning of the immune system in old age.

In young patients, white blood cell count (WBCC) used to diagnose infection. A raised white blood cell count is associated with the presence of infection. But recent retrospective studies have shown that in geriatric patients infection doesn’t come with a raise in white blood cells. In our present study we would like to confirm these results prospectively. For this we will collect data and blood counts from young and geriatric patients, with and without infection.

We also investigate wether certain clinical characteristics (cardiovascular risk factors, cardiovascular diseases, chronic cytomegalovirus infections, periodontitis, onychomycosis – a common fungus of the toe nail) are associated with a non-reaction of white blood cells to infection.

Course: We are inviting you to take part in this clinical study because your clinical status falls within the inclusion criteria of the study. This clinical study is to include 200 patients (from whom all in Belgium).

To be able to take part in this study you must present with an inflammation in your blood. This was analysed at your admission at the hospital. The inflammation must be paired with one of the following:

- A bacterial or viral infection
- An inflammatory disease: microcristalline arthritis (gout), a pulmonary embolism, rhabdomyolysis, or Crush syndrome

The exclusion criteria are: an immunosuppresive treatment (such as use of NSAIDs - eg Ibuprofen, corticosteroids, chemotherapy, immunotherapy), the presence of active cancer, antibiotic use before hospitalization, and hematological diseases. In the presence of dementia, we ask permission from the patient's family to include him / her in our study.

Your participation in the study will last 5 days. During this period Hanne Maes will ask you questions about your nutritional status, your activities of daily living, your memory, your demographic data (age, weight, height, gender), your medical history, your medication use, ... Completing these questionnaires will take you 30 minutes during the first consultation.

For 5 days we will collect the results of your blood analyses and other results of your laboratory tests.

During our first consultaton we will, ask you to pinch our instrument for analysing grip strength a couple of times, and take a look at your toenails for assessing onychomycosis (a common fungal infection of the toe nail).

Description of risks and benefits

As indicated above, neither the treatment that has been proposed nor the diagnostic and monitoring procedures for your clinical situation go beyond good medical practice. No risk, in terms of health, can be linked to your participation in this study.

Similarly, you should not expect any personal benefits as a result of taking part in the study. Know only that your participation will allow us to better understand the changes happening in the immune system with old age and to offer better diagnostic tools for diagnosing infection in geriatric patients in the future.

Withdrawal of consent

Your participation is voluntary and you are entitled to withdraw your consent to take part in the study for any reason, without having to justify your decision.

If you withdraw your consent to take part in the study, to guarantee the validity of the research, the data encoded up to the point at which you withdraw will be retained. No new data may be sent to the sponsor.

The sponsor/party responsible for the study may also decide to stop the study because the data collected provide a faster response than originally expected.

If you take part in this study, we ask you:

- To cooperate fully in the smooth running of this study.
- Not to conceal anything such as information relating to your state of health, the medication you are taking or the symptoms you are experiencing.
- To inform your doctor if you are asked to take part in another study to discuss with him/her the possibility of taking part in this study and to see whether you should then stop taking part in the present study.

Contact

If you need further information, but also if you have problems or concerns, you can contact the investigator (Maes, Hanne) or a member of his/her research team on the following telephone number: 0479 80 43 72.

If you have any questions relating to your rights as a participant in a clinical study, you can contact the patient rights ombudsman of your institution on this telephone number: 02 477 70 70, or ombudsdienst@uzbrussel.be. If necessary, he/she can put you in contact with the ethics committee.

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II Informed consent (2 pages)

Participant

I declare that I have been informed of the nature of the study, its purpose, its duration, the possible side effects and what is expected of me. I have taken note of the information document and the appendices to this document.

I have had sufficient time to think about it and discuss it with a person of my choice (GP, relative).

I have had the opportunity to ask any questions that came to mind and have obtained a favourable response to my questions.

I understand that data about me will be collected throughout my participation in this study and that the investigator and the sponsor of the study will guarantee the confidentiality of these data.

I agree to my personal data being processed as described in the section dealing with confidentiality guarantees (page x/y). I also consent to these data being transferred to and processed in countries other than Belgium.

I agree / do not agree **(delete as appropriate)** to the research data collected for the purposes of this study being processed at a later date provided this processing is limited to the context of the present study (better understanding of the disease and its treatment).

I agree / do not agree **(delete as appropriate)** to my GP or other specialists in charge of my health being contacted if required to obtain additional information about my health.

I have received a copy of the information to the participant and the informed consent form.

Surname, first name, date and signature of the volunteer.

Witness/Interpreter

I was present during the entire process of informing the patient and I confirm that the information on the objectives and procedures of the study was adequately provided, that the participant (or his/her legal representative) apparently understood the study and that consent to participate in the study was freely given.

Surname, first name and qualification of the witness/interpreter:

Date and signature of the witness/interpreter.

Investigator

I, the undersigned, Maes Hanne, investigator, confirm that I have verbally provided the necessary information about the study and have given the participant a copy of the information document.

I confirm that no pressure was applied to persuade the patient to agree to take part in the study and that I am willing to answer any additional questions if required.

I confirm that I operate in accordance with the ethical principles set out in the latest version of the “Helsinki Declaration”, the “Good Clinical Practices” and the Belgian Law of 7 May 2004 related to experiments on humans.

Surname, first name, date and signature of the investigator’s representative	Surname, first name, date and signature of the investigator

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III Supplementary information (2 pages)

1: Supplementary information on the organisation of the study

Overview of the different examinations:

During 5 days, we will collect results from bloodsamples and microbiological sample data. The first consultation we will collect questionnaires, a viral throat swab, clinical assessment of onychomycosis (a common fungal infection of the toe nail), and assessment of the grip strength with our measuring instrument (Martin vigorimeter).

2: Supplementary information on the protection and rights of the participant in a clinical study

Ethics Committee

This study has been reviewed by an independent Ethics Committee, namely the Ethics Committee of UZ Brussels, which has issued a favourable opinion. It is the task of the Ethics Committees to protect people who take part in a clinical trial. They make sure that your rights as a patient and as a participant in a clinical study are respected, that based on current knowledge, the study is scientifically relevant and ethical.
You should not under any circumstances take the favourable opinion of the Ethics Committee as an incentive to take part in this study.

Voluntary participation

Before signing, do not hesitate to ask any questions you feel are appropriate. Take the time to discuss matters with a trusted person if you so wish.

Your participation in the study is voluntary and must remain free of any coercion: this means that you have the right not to take part in the study or to withdraw without giving a reason, even if you previously agreed to take part. Your decision will not affect your relationship with the investigator or the quality of your future therapeutic care.

If you agree to take part in this study, you will sign the informed consent form. The investigator will also sign this form to confirm that he/she has provided you with the necessary information about the study. You will receive a copy of the form.

Costs associated with your participation

You will not receive any compensation for your participation in this study. Furthermore, the study will not involve any additional costs for you.

Guarantee of confidentiality

Your participation in the study means that you agree to the investigator collecting data about you and to the study sponsor using these data for research purposes and in connection with scientific and medical publications.

You are entitled to ask the investigator what data are being collected about you and what is their use in connection with the study. This data concerns your current clinical situation but also some of your background, the results of examinations carried out within the context of care of your health in accordance with current standards. You have the right to inspect these data and correct them if they are incorrect.

The investigator has a duty of confidentiality vis-à-vis the data collected.

This means that he/she undertakes not only never to reveal your name in the context of a publication or conference but also that he/she will encode your data before sending them to the manager of the database of collected data (Hanne Maes, VUB, UZ Brussel).

The investigator and his/her team will therefore be the only ones to be able to establish a link between the data transmitted throughout the study and your medical records.

The personal data transmitted will not contain any combination of elements that might despite everything allow you to be identified.

For the study data manager designated by the sponsor, the data transmitted will not allow you to be identified. The latter is responsible for collecting the data gathered by all investigators taking part in the study, processing them and protecting them in accordance with the requirements of the Belgian law on the protection of privacy.

To verify the quality of the study, it is possible that your medical records will be examined by third parties (ethics committee, representatives of the study sponsor, external auditors). In any event, this may only take place under the responsibility of the investigator or of one of his/her colleagues and by persons subject to the obligation of professional secrecy.

These (encoded) data will be able to be sent to Belgian or other regulatory authorities, to the relevant ethics committees, to other doctors and/or to organisations working in collaboration with the sponsor.

They will also be able to be sent to other sites of the sponsor in Belgium and in other countries where the standards in terms of the protection of personal data may be different or less stringent.

Your consent to take part in this study therefore also implies your consent to the use of your encoded medical data for the purposes described in this information form and to their transmission to the aforementioned people and authorities.

The sponsor will use the data collected within the context of the study in which you are taking part, but would also like to be able to use them in connection with other research concerning the same disease as yours and its treatment. Any use of your data outside the context described in this document is only possible with the approval of the ethics committee.

If you withdraw your consent to take part in the study, to guarantee the validity of the research, the data encoded up to the point at which you withdraw will be retained. No new data may be sent to the sponsor.

Insurance

In an observational study, the only possible risk would be a flaw in the measures taken to protect the confidentiality of the private information about you. Even without fault, the sponsor accepts responsibility for damage caused to the participant (or his/her dependants) and linked directly or indirectly to participation in this study. In this context, the sponsor has taken out an insurance contract (name of the insurance company, policy number, contact details).