Novartis Norge AS

Clinical trials - something for you?

Information for participation in clinical trials

Introduction

Choosing whether or not to participate in a clinical trial is an important and personal choice. The information in this pamphlet will hopefully be able to help. It has been written for you, either as a patient, relative or friend who is interested in finding out more about clinical trials in Norway.

Contents

1 | Why should I participate in a clinical trial?

Clinical trials is research on the effect of new treatment methods, and on whether the side effects are acceptable.[1]

By participating in a clinical trial, you are taking an active role in your own illness. In some cases, you may gain access to new treatments before they become available to others. It is important to note that the treatment you receive may be new, and thus the effect is not known. Therefore, not everyone may benefit from the treatment; however, your participation may contribute towards helping others who have the same illness as you, both in Norway and in other countries.

There will always be a certain risk involved in participating in a clinical trial, and therefore you must assess both the possible benefits and risks associated with participating. The treatment may have side effects that are both known and unknown. As the clinical trial proceeds, new knowledge may arise that is significant to the assessment of the benefits and risks involved in your participation. As a participant, you will receive thorough information before, during and after the trial period. You may, at any time, choose to withdraw from the trial without having to provide any further reasons.

An **informed consent form** (see chapter 9) has been prepared, in order to allow possible participants to gain an understanding of what the clinical trial is about. As a participant, your informed consent is a prerequisite for allowing the trial to be conducted.

2 | What is the aim of performing a clinical trial?

Clinical trials usually aim to answer important research questions, such as:

- Which dose of the drug provides the best effect?
- How does the treatment impact the illness (is it improved or worsened)?
- How well does my body tolerate the trial treatment?
- Which side effects are connected to the treatment?
- What is the effect over time?

During the course of the trial, more information will be gathered about the treatment and the risks connected to the treatment, as well as how effective or ineffective the treatment is.

The safety of the drug is assessed using laboratory tests, image diagnostics and various function tests.

The effect of the drug is assessed based on measuring systems that are prepared for the illness in question.

3 | Where can I find information about clinical trials in Norway?

https://helsenorge.no/kliniske-studier/ is the public healthcare portal for Norwegian citizens.[2] Here you are also able to find information about some clinical trials that are being conducted in Norway, and which terms and rights are connected to participation. The e-health directorate is responsible for the operation and development of the website.

https://helsenorge.no/kliniske-studier/

https://clinicaltrials.gov is another useful website.[3] It is owned by the US National Library of Medicine in the USA, and is an international registry of publicly and privately financed trials that are being conducted all over the world.

https://clinicaltrials.gov/

The information on both of these websites is regularly updated, but not necessarily at the same time. Check both of the websites regularly if you are interested in clinical trials that are being conducted on special illnesses or areas of disease. It may also be beneficial to involve your doctor, who will be able to help you with any questions that you may have. If necessary, your doctor can speak directly to the people responsible for the trial and gain more information.

4 | Am I able to participate in a clinical trial?

The criteria for participation vary from trial to trial. **Inclusion criteria** are criteria that must be fulfilled in order for you to participate. **Exclusion criteria** are criteria that exclude participation. The criteria may revolve around age, sex, type of illness, degree of illness, previous treatment, other medical disorders, and results from various tests and examinations.

Inclusion and exclusion criteria are not used to discriminate, but rather to find the participants best suited for this exact clinical trial. Participants are carefully selected in order to ensure that the proper illness parameters are measured, and to discover whether the drug has an effect on the investigated illness during the trial. The Principal Investigator will discuss these criteria with you, in order to assess whether you are able to participate.

5 | Am I able to join a clinical trial at any time?

The inclusion and exclusion criteria are not the only deciding factors for whether you are able to participate. **The recruitment period** is also a determining factor.

The recruitment period is the designated period in which a search is conducted for trial patients. The duration of **the recruitment period** may be dependent on the number of patients that are necessary to include in the trial to document whether it has an effect, and how far one has come in the development of the drug, etc. Once **the recruitment period** is over, it is no longer possible to participate.

6 | What rights and what responsibilities do I have as a clinical trial participant?

You choose whether you wish to participate. You have the right to receive factual information before, during and after the trial, and you have the right to ask the Principal Investigator questions at any time. Contact information for the Principal Investigator will be listed in the papers you receive.

If you choose to participate in the trial, you will be asked to confirm this by signing **the informed consent** form (chapter 9). Once you have given your consent, you are expected to follow the guidelines contained within the informed consent, as this pertains to your own health. You are able to change your mind at any time. You are not required to provide any explanation as to why you do not wish to participate, or why you are withdrawing your consent. If you do not wish to participate, your doctor will inform you of the best available treatment and monitor you in the usual manner.

As a trial participant, you are expected to follow the trial's procedures, meet at the agreed upon time, and follow the treatment. Please remember to inform the Principal Investigator about:

- your health status
- medication that you have used (with or without a prescription)
- which other drugs you may be currently taking
- any newly arisen symptoms

7 | Who will I meet as a clinical trial participant?

The doctor responsible for the trial and **trial team** are called the **Principal Investigator. The trial team** may consist of other doctors, nurses, coordinators, technicians, and healthcare and social workers. The Principal Investigator is able to delegate tasks to others within the **trial team**, but is still responsible for the trial being conducted in the proper manner.

The trial team assesses your health status before the trial begins, gives you detailed instructions on what you need to do, monitors you, and gives you information as the trial progresses. The number of consultations and examinations will vary, but usually you will have more consultations than you regularly would if you were not part of the trial.[4] In some cases, **the trial team** will keep in contact with you even after the trial has come to an end. You will work closely with **the trial team**, in order to ensure that the trial is being conducted as planned.

Your GP/doctor also has an important role, even though he/she is not a direct part of **the trial team**. Therefore, it is recommended that you discuss any trial participation with your doctor, and that you keep your doctor updated on the trial's progress.

If you have an appointment with your GP/ doctor during the trial period, you must inform him/her that you are participating in the trial. If the doctor prescribes new treatment, this treatment must be in accordance with **the trial protocol**. If your doctor discovers new symptoms, **the trial team** must be informed of these. You will be given information that you can give to your doctor.

8 | How is my privacy secured?

Many clinical trials are initiated and paid for by a pharmaceutical company. The pharmaceutical company is defined as the trial's **sponsor**, and will be responsible for a lot of the practical aspects of the trial, even if the healthcare staff at your hospital or doctor's office are the people actually performing the trial. The **sponsor** is also responsible for complying with national and international privacy directives. All staff involved in the trial has a confidentiality obligation, and must follow strict rules of confidentiality.[5]

All of your personal information, medical information, and test results that are collected in connection with the trial, are **anonymised**, i.e. name and social security number are deleted and replaced by a new number. Only the **Principal Investigator**, i.e. the doctor conducting the trial, is able to trace which persons are connected to which code via a so-called **identification key**. The trial's **sponsor** does not have access to the identification key. It is the **sponsor's** responsibility to follow Norwegian privacy policies for personal information and tests that are sent abroad. In some cases, the **Principal Investigator** must provide approval authorities, i.e. the Norwegian Medicines Agency, the regional committees for medical and health research ethics (REK) and/or the sponsor, access to personal and medical information. This is only done in connection with a review of the entire trial.

9 | Informed consent

The **informed consent** form contains information about the trial, and has been created for people who are interested in participating in the trial. The form must be written in language that is easy to understand, and may not contain any difficult and technical words. Please ask for help if you are unsure or do not understand something. Take the time to ask the Principal Investigator, or other people you trust, any questions that you may have.

The regional committee for medical and health research ethics (REK) has a template for patient information and consent that must be adhered to.[6] All material connected with the trial must be reviewed in the **informed consent** form, and be approved by the regional committee for medical and health research ethics before the trial begins.

The template for patient information covers the following points:

- The purpose of the trial
- Who is responsible?
- What does the project entail?
- Potential advantages, disadvantages and serious side effects
- Voluntary participation and the possibility to withdraw consent
- What happens to your tests and information?
- What type of information may any genetic examinations in the project provide?
- Financing
- Insurance
- Information about the results of the study
- Approval
- Contact information
- Consent

If you choose to participate in a clinical trial with trial treatment, you must sign the **informed consent** form. Children and young people below the age of 18, and adults who are not able to make independent choices, are considered to be vulnerable groups. Therefore, different requirements for informed consent are placed on them. The Principal Investigator will be able to answer your questions about this.

10 | What happens if the clinical trial changes my health status?

During the course of the trial period, and any longer follow up period, all changes to your illness and health status must be reported to **the trial team**, as specified in the obligations you agreed to (see chapter 6). If the clinical trial becomes part of a so-called blind, randomised study (see chapter 14), using a **placebo** (a product without medical effect) or control drug, you will be informed of which drug you received only once the trial is complete. The one exception is for side effects and other health-related events that require the blind to be lifted (see chapter 14).

If your health status changes, the Principal Investigator may adjust your treatment, depending on the **trial protocol**.

11 | What type of treatment will I receive once the clinical trial is over?

The main principle is that you should not receive the clinical trial beyond the trial period. The Principal Investigator will explain which treatment alternatives are available, and will guide you in choosing the best possible treatment.

For some clinical trials, an extension phase is planned. During this time, you will still be able to receive the trial drug, but not necessarily until it enters the market. This is generally described in the patient information that you receive before the trial begins. The Principal Investigator can provide you with more information on this.

12 | How are expenses related to the clinical trial covered?

You will not receive payment for participating in clinical research, and no type of fee or reimbursement may be demanded. It will not cost you to receive the trial treatment, but you may have to cover some costs related to travel and loss of work time.

13 | Which authorities assess whether the clinical trial may be conducted?

Clinical trials in Norway is subject to international and Norwegian guidelines and provisions. These provisions ensure the rights, health and welfare of all the trial participants, and that the trial data collected is reliable and used in the correct manner. All the parties involved are obliged to follow these provisions carefully.

Ethics committees in each healthcare region consist of doctors, other researchers, professionals and laymen, who are responsible for ensuring that all patients who participate in trial treatment are ensured of their rights, health and welfare. These are called the regional committee for medical and health research ethics **(REK)**.[7] These are regulated via the EU provision 536/2014.[8]

The Norwegian Medicines Agency[9] is the Norwegian government authority responsible for approving and checking drugs, and assessing the quality, safety and effect of drugs and medical equipment. The Norwegian Medicines Agency registers, assesses and monitors all trial treatments in Norway.

Clinical research in Norway is subject to approval from **REK** and the **Norwegian Medicines Agency**.

14 | What is trial design?

The way in which clinical trials are set up is often referred to as **trial design. Trial design** is decided based on which research questions need to be answered.

In order to assess the effect of a drug, it may be necessary to compare it to a "dummy treatment", also called a **placebo**, or to another drug, also often referred to as an **active comparator**. For the comparison to be conducted without impact from other factors, the patient is arbitrarily placed - in a randomised manner - into a **treatment arm**.

Randomisation is the process in which patients who participate in the trial are placed into a group that either receives the trial treatment, the **placebo**, or the **active comparator**.

Blind treatment means that the trial staff and/or patients are not aware of which treatment is being provided.

Single-blind means that only the patient is unaware of which treatment they are receiving.

Double-blind means that neither the patients nor the trial staff know which treatment is being provided. This is done in order to eliminate the chance that preconceived ideas affect the interpretation of the results.

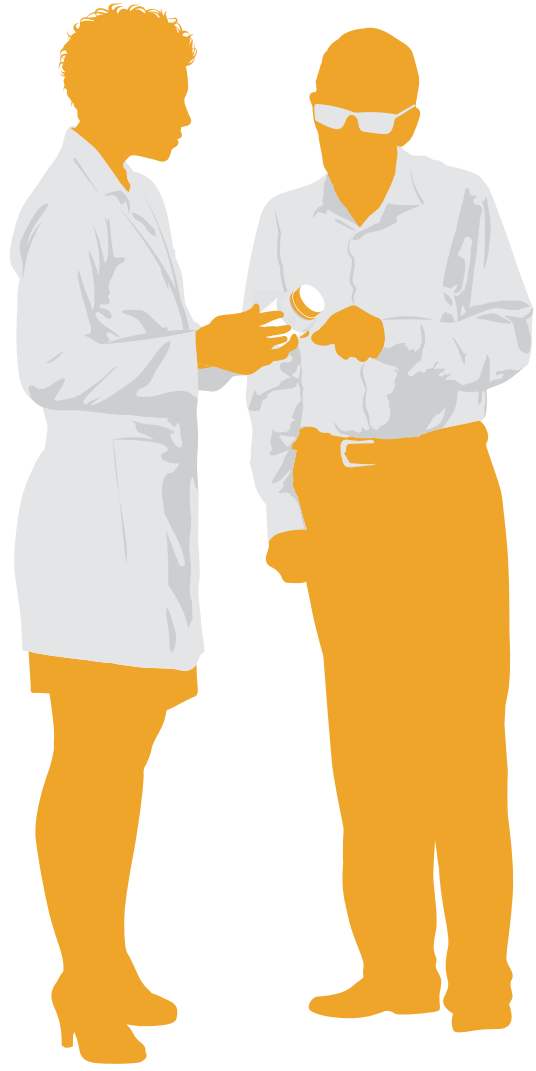
Unblind, open treatment means that both the trial staff and the patients know which treatment is being provided. This is often done during an extension phase of a blind study, or where it is appropriate that everyone is aware of which treatment is being provided.

15 | What happens once the clinical trial is over?

Once the trial is complete, all the information and results will be analysed before a final assessment on the trial treatment's effect and safety is made. The results of the trial will later be published in scientific journals and be made publicly available. The deadline for this, and what shall be published, is regulated via the EU provision 536/2014.[8]

The results of the trial must be sent to the authorities that approved the trial, i.e. the ethics committee and the Norwegian Medicines Agency, and be registered on public websites such as https://clinicaltrials.gov.[3]

Application for marketing authorisation may be sent to the Norwegian Medicines Agency when the safety and effect has been documented via studies. Once all the data has been analysed, you may ask the Principal Investigator for the findings of the trial.



16 | Glossary

Active comparator - a drug that already exists on the market. Used as a reference for the trial drug, to assess the relative effect of the trial treatment.

Anonymised - all personal information, medical information, and test results that are collected in connection to the trial, i.e. name and social security number are deleted and replaced with a new number.

Treatment arm - the trial treatment that defines the group of participants who receive this particular treatment/dose.

Blind treatment - the trial staff and/or patients do not know which treatment is being provided.

Blind randomised trial - patients are placed into a group that either receives the trial treatment, the placebo, or the active comparator, but the patients do not know which group they belong to.

Double-blind trial - neither the patients nor the trial staff know which treatment (trial drug, placebo, or active comparator) is being given.

Exclusion criteria - factors that determine that you are not suited to participate in the trial. These are important to identify participants who potentially have a higher risk of side effects by participating in the trial, and other factors that may impact the accuracy of the trial results.

Single-blind - a trial where only the patient is unaware of which treatment (the trial drug, placebo or active comparator) they are receiving.

Ethics committees - independent committee that consists of various experts such as doctors, biologists, laymen and lawyers. The committee reviews the scientific, ethical and legal aspects of the trial to ensure that the trial participants' safety is safeguarded.

Principal Investigator / Trial Doctor - the doctor responsible for the trial

Identification key - only the Principal Investigator, i.e. the doctor responsible for the trial, has the possibility to trace who is connected to which code via a so-called identification key.

Informed consent - given by the patient to show that they have received sufficient information about the trial, and that they wish to participate. The consent is documented by the patient signing the informed consent form. The form has been developed by the trial sponsor.

Inclusion criteria - the factors that must be met in order to participate in the trial. These are important to identify participants who may potentially benefit from participating in the trial.

Clinical trial - trials performed on humans in order to investigate the effect of drugs or other methods of treatment, but also to investigate how drugs are converted in the body, and whether the side effects are acceptable.

Placebo - a product with no medical effect, which is used in the trial as a comparison to the trial drug, in order to assess the relative effect of the trial drug.

The protocol / trial protocol - a plan which describes, in detail, how the trial will be conducted.

Randomisation - the process in which patients who participate in the trial are randomly placed in a group that either receives the trial treatment, the placebo, or the active comparator.

REK - The regional committee for medical and health research ethics.

The recruitment period - the period of time during which a search for trial patients is conducted.

Sponsor - the person or organisation that is responsible for organising a clinical trial.

The Norwegian Medicines Agency - the Norwegian government authority responsible for approving and checking drugs, and assessing the quality, safety and effect of drugs and medical equipment.

Trial design - the manner in which the trial is set up. The trial design is determined based on which research questions the trial wishes to answer.

The trial team - the group of people involved in conducting the trial, under the management of the Principal Investigator. The trial team consists of the Principal Investigator, other doctors, nurses, coordinators, technicians, and other healthcare staff and social workers.

Unblind / open - both the trial staff and the patients know which treatment is being provided.

17 | Sources

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LHL

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Forbundet for deg med migrene
og andre hodepinesykdommer

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