SERVIER

Clinical Trial Summary

An experimental medicine clinical study to compare peripheral immune system from subjects without cancer diagnosis and patients with solid tumours

Full scientific title: An experimental medicine, low grade interventional, clinical study to compare peripheral immune system from subjects without cancer diagnosis and patients with advanced solid tumours

We thank all the participants who took part in the study. Clinical study participants are very important for making progress in science, for the benefit of patients.
This document is a summary of the study. It is written for a general audience.

Researchers need many studies to decide which medicines work the best and are the safest for patients. For medical science to progress, many studies involving participants are running all around the world. This summary only shows the results from this one study. If you have any questions about this study, please talk to your doctor.

Therapeutic area:
Oncology

Disease:
Solid tumours

Study phase:
Not Applicable

Final Version
03/04/2024

In this summary:

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1 Why was this study done?

The immune system (made of organs, certain blood cells, proteins and other substances) is designed to defend the body against foreign or dangerous invaders including abnormal cells. In some cases, abnormal cells can escape the control of the immune system. This may lead to the development of cancer. At this stage, the immune system may be prevented from functioning properly by the tumour itself to promote the growth of the cancer. It is therefore important to understand what goes wrong with the immune system to discover new treatments for cancer.

This study was done to gain knowledge on components of the immune system from persons without cancer diagnosis and persons with cancer. The participants did not receive any treatment as part of this study.

The main aim of the study was to find out if the levels of certain immune system components (called immune profile) are similar between participants without cancer and those with advanced solid tumour cancer.

Solid tumour cancers are abnormal growths of cells in organ(s) of the body such as the lung, liver, or colon. In advanced stages of disease, solid tumours may spread in the body.

2 When and where did this study take place?

When did the study take place?

- This study started in November 2021.
- It ended in April 2023.

Where did the study take place?

The study took place in France.

3 Who participated in the study?

Which participants were included in the study?

To take part, participants had to:

- Be 45 to 70 years of age.
- Belong to one of the 4 groups:
- For group 1
  - Have a specific type of lung cancer called non-small cell lung cancer.
- For group 2
  - Have colorectal cancer. Colorectal cancer is a cancer that starts in the large bowel and involves the rectum (the lowest part of the gut).
- For group 3
  - Have cancer of the pancreas (the organ lying behind the lower part of the stomach that produces digestive substances and certain chemical substances called hormones).
- For group 6
  - Be an individual without cancer diagnosis.

Due to difficulties to find new participants, the 2 optional groups planned (group 4 and group 5) were not opened.

How many participants took part in the study?

A total of 36 participants took part in the study: 18 women and 18 men.

How old were the participants?

The average age of the participants was 62 years. The youngest participant was 47 years old and the oldest was 82 years old.

4 Which treatments did the participants receive?

Participants did not receive any study drug during the study.

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5 How was the study carried out?

A total of 36 participants took part in the study as follows:

- Group 1: 8 participants
- Group 2: 7 participants
- Group 3: 9 participants
- Group 6: 12 participants

The participants started with a first period called a screening period that could last up to 28 days. This period allowed doctors to check if the participant fulfilled all the criteria to take part in the study.

Then, one or two blood samples (depending on the group) were collected from the participants.

After blood sampling, participants were followed-up for safety for 30 days. This monitoring period assessed the potential side effects that study procedures may have caused.

On average, the study duration lasted 1 month for all participants.

6 What were the side effects?

Side effects are unwanted medical events that the doctors think may be caused by the treatments or study related procedures in the study.

In this study, only side effects related to study procedures (tests and blood collections) were considered, because there was no study drug intake.

The results may be presented differently in other documents related to the study.

The table below shows the number of participants who had procedure-related side effects.

	Out of 36 participants
Participants who had procedure-related side effect(s)	3 (8%)
Participants who had serious*procedure-related side effect(s)	0 (0%)
Participants who stopped the study because of procedure-related side effect(s)	0 (0%)

**See definition of serious side effects below*

What were the types of side effects?

The table below shows the procedure-related side effects reported in the study. All of them were reported in group 6.

	Group 6 Out of 12 participants
Bruising at the injection site	2 (17%)
Increase in blood pressure	1 (8%)

= *participants*

What were the serious side effects?

A procedure-related side effect is considered serious when:

- the participant needs to be hospitalised,
- it causes lasting damage or death,
- the participant's life is in danger or,
- it is medically important in the doctor's opinion.

In this study, no participants had procedure-related serious side effects (serious unwanted medical events thought to be caused by the study related procedures in the study).

None of the participants died during the study because of an unwanted event thought to be caused by the study related procedures.

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7 What were the study results?

The study stopped including participants earlier than planned since it was difficult to find new participants.

This document presents only the results for the main aim of the study.

The study could not show that participants with cancer and those without cancer had similar immune profile. The reason may be that there were few participants in each group and that the results varied a lot between participants.

8 How has this study helped research?

The study helped researchers gather more information on the components of the immune system of participants with cancer and those without cancer.

This summary shows only the main results from this one study.

9 Are there plans for further studies?

No other studies with this design are planned so far.

10 Further information

What are the identification numbers of the study?

- Protocol code: CL1-ONCO-001
- US NCT number: NCT05133128

Who did the study?

The company that organised and funded the research, called the "sponsor", is the Institut de Recherches Internationales Servier based in Suresnes, France.

How can you contact the sponsor?

Contact us on the Servier website https://servier.com/en/

Where can you learn more about this study?

You can find more information about this study on these websites:

- https://clinicaltrials.servier.com/find-clinical-trials
- https://www.clinicaltrials.gov

In this document we translated medical terms into lay terms. You can find the corresponding medical terms in the Servier glossary at https://clinicaltrials.servier.com/glossary/

You can find general information about clinical trials on https://clinicaltrials.servier.com/