



CLINICAL STUDY RESULTS

A study to learn about the safety and effects of ICT01 in combination with interleukin-2 (IL-2) in people with advanced solid tumours (EVICTION 2)

The results from this clinical study suggest that ICT01 when used together with IL-2, with or without pembrolizumab, was safe and well tolerated in participants with advanced cancer.

These results are from one clinical study only. Other clinical studies may produce different results.

This lay summary was created by Ipsen with the assistance of a third-party writing service provider.

What was the study about?

The purpose of this study was to learn about the safety and effects of ICT01, also known as IPN60340, when used together with interleukin-2 (IL-2), with or without pembrolizumab, in people with advanced solid tumours.

Advanced solid tumours are cancers that grow to form a lump or mass in the body and have spread from where they started or have kept growing after earlier treatment.

The treatments used in this clinical study act as immunotherapy agents. Immunotherapies help the body's immune system to fight and kill cancer cells.

ICT01 is a new immunotherapy treatment for advanced solid tumors. It works by helping immune cells to find and destroy cancer cells. In this study, ICT01 was tested together with two other cancer medicines called IL-2 and pembrolizumab.

IL-2 is a medicine that helps increasing the number and activity of immune cells that may help the body fight cancer. Pembrolizumab helps the immune system find and kill cancer cells. Together, these treatments may strengthen the immune system to find and destroy cancer cells.

The study had 2 parts: **Part 1** and **Part 2**.

Part 1 tested how safe and well tolerated different doses of ICT01 were when given together with IL-2, with or without pembrolizumab, to people with certain types of advanced solid tumors.

Part 2 was designed to learn the effects of ICT01 when given with IL-2, with or without pembrolizumab. The purpose was to look at how well the treatments could shrink the tumours or stop them from growing. The Sponsor reviewed all safety, efficacy, and pharmacodynamics results from Part 1 and decided to terminate the study. Safety events observed were consistent with the known side effects of ICT01 and other treatments used in this study.

The aim of the study was to learn how safe and well tolerated ICT01 was in people with advanced solid tumors:

- when given together with IL-2, and
- when given together with IL-2 and pembrolizumab.

The study took place between May 2022 and October 2025 at 5 study sites in France, Germany and the United Kingdom.

Who took part in this study?



44

PARTICIPANTS



28

MEN



16

WOMEN



57 YEARS
AVERAGE
AGE

To take part in the study, participants had to:



- be aged 18 years or older,
- be diagnosed with colon cancer, womb cancer, prostate cancer, pancreatic cancer, or skin cancer, and have failed 2 previous treatments
- have at least one tumour that can be measured,
- be able to move and perform light work, and
- have a life expectancy of more than 3 months.



Participants could not take part in the study if:

- they had existing health condition(s) or were on treatment(s) that could affect the results of the study.

What treatments were used in this study?

Study Treatment

ICT01 was given at different doses as a drip through a vein, once on Day 1 of every 21-day cycle. Some participants also received ICT01 once on Day 8 of Cycles 1 to 3.

IL-2 was given at a dose of 1 or 2 MIU/m²* as an injection under the skin daily from Days 1 to 5 in Cycles 1 to 3.

Pembrolizumab was given to some of the participants at a dose of 200 mg as a drip through a vein once on Day 1 of every cycle.

***Note:** MIU/m² means million international units per square meter. This is a way of calculating the amount of medicine needed for each person.

Part 1 had 3 periods:

Screening period: The study doctor checked if participants could take part in this study. This was done within about 1 month before they started the study treatment.

Treatment period: Participants received one of the treatments listed below. Treatment was given in cycles that lasted 21-days:

- **Treatment Combination 1:** 38 participants were treated in 12 different groups (Groups 1 to 12).
 - **Participants in Groups 1 to 9** received 1 dose of ICT01 on Day 1 and 1 dose of IL-2 every day on Days 1 to 5 for the first 3 treatment cycles. From Cycle 4 onwards, they only received 1 dose of ICT01 on Day 1 of each cycle.
 - **Participants in Groups 10 to 12** received 1 dose of ICT01 on Day 1 and Day 8 and 1 dose of IL-2 every day on Days 1 to 5 for the first 3 treatment cycles. From Cycle 4 onwards, they only received 1 dose of ICT01 on Day 1 of each cycle.
- **Treatment Combination 2:** 6 participants were treated in 3 different groups (Groups 13 to 15).
 - **Participants in Groups 13 and 14** received 1 dose of ICT01 on Day 1 and 1 dose of IL-2 every day on Days 1 to 5 for the first 3 treatment cycles. They also received 1 dose of pembrolizumab on Day 1 of each cycle. From Cycle 4 onwards, they only received 1 dose of ICT01 and pembrolizumab on Day 1 of each cycle.
 - **Participants in Group 15** received 1 dose of ICT01 on Day 1 and Day 8 and 1 dose of IL-2 every day on Days 1 to 5 for the first 3 treatment cycles. They also received 1 dose of pembrolizumab on Day 1 of each cycle. From Cycle 4 onwards, they only received 1 dose of ICT01 and pembrolizumab on Day 1 of each cycle.

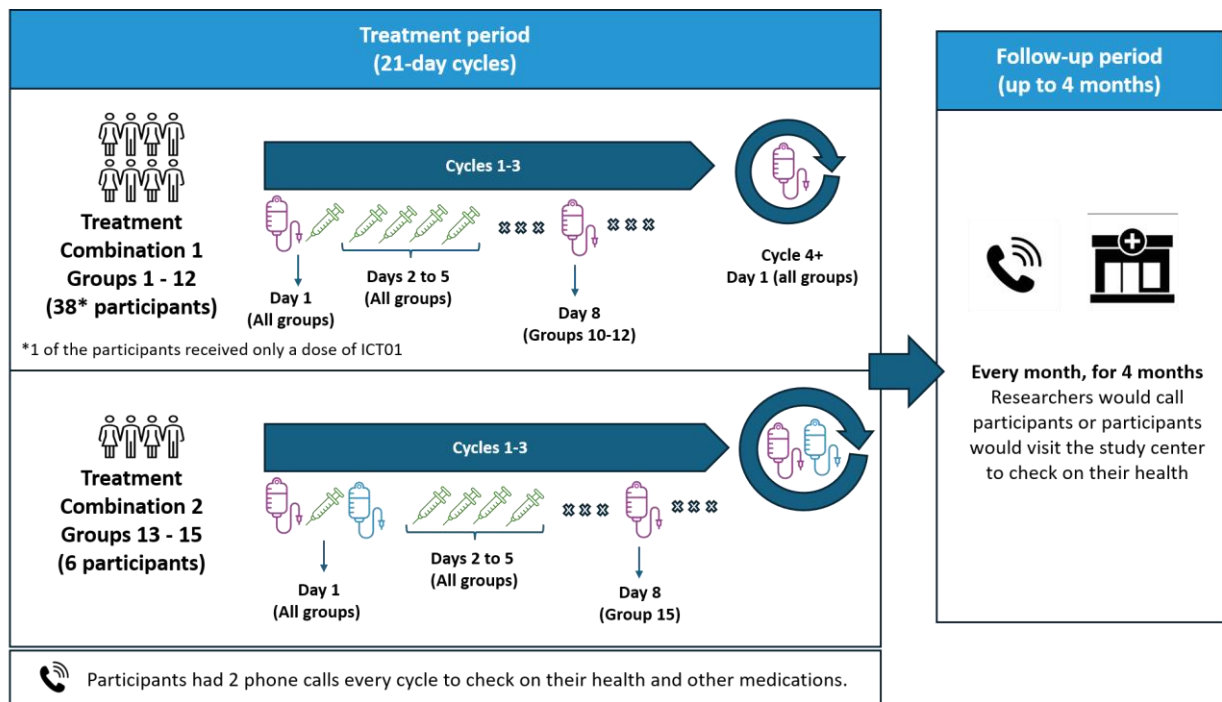
The ICT01 doses were gradually increased in small groups of participants. Participants continued the treatment as long as the study doctor thought it was right for them, they could tolerate it, and their cancer did not get worse.

This study was 'open label'. This means that the researchers and the participants knew which treatment they received.

Every cycle, the study team called participants to check their health, whether they had any side effects, and any medications they might have taken after receiving the treatment.

Follow-up period: Researchers called the participants to check their health, or the participants visited the hospital every month, for 4 months after the last dose of study treatment.

The figure in this section shows how was the study was done.



What did researchers find out in the study?

All participants (44 participants) had at least one medical problem while they were being treated in the study.

ICT01 together with IL-2, with or without pembrolizumab, was safe and well-tolerated in adults with advanced cancer.

How many participants had dose-limiting toxicities?

Dose-limiting toxicities, or 'DLTs', are side effects caused by the study treatments that are serious enough for the dose to be lowered or the treatment be stopped. During the study, researchers recorded DLTs in all participants.

No DLTs were reported during the study.

How many participants had medical problems?

Medical problems any health changes reported during the study, whether or not they were related to the study treatment. A medical problem is 'serious' if it results in death, is life-threatening, causes long lasting problems, or leads to hospitalisation. A medical problem is considered 'severe' if additional medical care, treatment, or close monitoring is needed.

The researchers also looked at the results from laboratory tests, vital signs (blood pressure, body temperature, heart rate, and levels of oxygen in the blood), physical examinations, and electrocardiograms (ECGs). An ECG is a test of the heart's activity.

All participants (44 participants) had at least one medical problem while they were being treated in the study.

22 out of 44 participants had at least one severe medical problem.

Overall, 16 out of 44 of participants had at least one serious medical problem during the study.

One participant who was treated with ICT01 together with IL-2, died during the study because of a serious medical problem. The serious medical problem was an infection caused by food, liquid, or saliva in the lungs (aspiration pneumonia). The study doctors did not consider this death to be related to the study treatment.

No clinically meaningful changes were seen in the laboratory tests, vital signs, and physical examinations. One participant experienced changes in their heartbeat (atrial fibrillation) and had a heart attack (myocardial infarction) when they received ICT01.

How many participants had to stop the treatment or leave the study because of a medical problem?

In this study, 3 out of 44 participants stopped the study treatment because of a medical problem when they received ICT01 and 2 out of 44 participants stopped the study treatment because of a medical problem when they received IL-2. None of the participants stopped the study treatment when they received pembrolizumab.

How many participants had tumours that got smaller or stopped growing after receiving the study treatment?

Researchers looked at the tumours of participants who had received at least 3 cycles of ICT01 together with IL-2, with or without pembrolizumab. In this group, 11 out of 33 participants had tumours that got smaller or stopped growing.

The results were similar when researchers looked at all participants who received at least 1 dose of the study treatment.

How did the treatment make participants feel?

During the study, participants were asked to tell the study team if they felt unwell, had any kind of medical problems, or noticed any changes in their bodies. These are called 'adverse events'.

Researchers recorded all adverse events reported by participants, even if they were not caused by study treatment. For example, if some participants caught COVID-19, this was recorded as an adverse event, even though it was not caused by the study treatment.

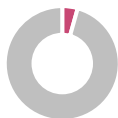
If the study doctor thought an adverse event may be linked to the study treatment, it was called a 'side effect'. A side effect is 'serious' when it is life-threatening, causes long lasting problems, or the participant had to go to hospital.

- 7 out of 44 of participants experienced at least one serious side effect when they received ICT01 and 5 out of 44 participants experienced at least one serious side effect when they received IL-2.
- No participants had serious side effects when they received pembrolizumab.
- No participants died due to a side effect during the study.

Overall, side effects were observed in:

- **41 out of 44 participants** when they received **ICT01**
- **40 out of 44 participants** when they received **IL-2**
- **4 out of 6 participants** when they received **pembrolizumab**

The most common serious side effects are shown in the table below as the actual number of participants in the group (1 out of 15).

Side Effects	ICT01 (44 Participants)	IL-2 (44 Participants)
Immune reaction that causes widespread inflammation (cytokine release syndrome)	3 out of 44 	2 out of 44 
Reaction during or shortly after receiving a treatment by infusion (infusion related reaction)	2 out of 44 	2 out of 44 

None of the participants had serious medical problems when they received pembrolizumab.

The most commonly reported side effects in participants who received ICT01 are shown in the following table.

Side Effects	ICT01 (44 Participants)
Immune reaction that causes widespread inflammation throughout the body (cytokine release syndrome)	20 out of 44 
Reaction during or shortly after receiving a treatment by infusion (infusion related reaction)	15 out of 44 
Low levels of a type of white blood cell called lymphocytes (that protect from infection)	10 out of 44 
Feeling sick	9 out of 44 
Increase in levels of a liver protein (enzyme) called alanine aminotransferase (ALT) in the blood	9 out of 44 

After receiving IL-2, the most common side effects participants had were an immune reaction that causes widespread inflammation throughout the body, fever, and reaction at the injection site.

After receiving pembrolizumab, the most common side effects participants had were an increase in the levels of a type of white blood cell called eosinophils, and an increase in the levels of liver enzymes.

More information

To learn more about this study, please visit:

- [ClinicalTrials.gov](https://clinicaltrials.gov) and search for study NCT05307874 or
- [Search for clinical trials - EMA \(euclinicaltrials.eu\)](https://searchforclinicaltrials-ema.euclinicaltrials.eu) and search for study 2024-514758-65-00.

For more information about current treatments available, please speak to your healthcare provider. If you have any questions about this study, please contact the sponsor, Ipsen at:



clinical.trials@ipson.com

Future research

There is no future research planned with ICT01 in solid tumours.

Study identification and other information

FULL STUDY TITLE: A Two-Part, Open-Label, Clinical Study to Assess the Safety, Tolerability and Activity of Intravenous Doses of ICT01 in Combination with Low-Dose Subcutaneous Interleukin-2 in Patients with Advanced Solid Tumors (EVICTION-2)

STUDY NUMBERS: Europe: 2024-514758-65-00| United States: NCT05307874|

PROTOCOL: ICT01-102

OTHER INFORMATION: Phase I studies are conducted with small numbers of participants. This helps researchers figure out the dose of the study drug to use in future studies, to understand what happens to the study drug in the body, and how safe it is.

We thank all the volunteers who took part in this study. Without their support, advances in treatments for medical conditions would not be possible.

We would also like to thank the people who took the time to review this document to make it easier for a general audience to read.