Clinical Trial Summary

TALLISUR – A study evaluating the effect of treatment with Trifluridine/Tipiracil on quality of life of patients with a specific type of bowel cancer after market authorisation

Full scientific title: Prospective, Multicenter, Open-label Phase IV trial of Trifluridine/Tipiracil to Evaluate the Health-related Quality of Life in Patients with Metastatic Colorectal Cancer

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 patients are running all around the world. This summary only shows the results from this one study. Other studies, evaluating the same drug, may find different results. You should not change your current treatment based on the results of this single study. If you have any questions about this study, please talk to your doctor.

Therapeutic area:
Oncology

Disease:
Metastatic colorectal cancer

Study phase:
IV

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Version
1.0

In this summary:

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1 Why was this study done?

The aim of this study was to investigate the impact of trifluridine/tipiracil on the quality of life of patients with cancer of the large intestine, so-called colorectal cancer.

Colorectal cancer is a disease which is caused by abnormal growth of cells in the large intestine. If the cancer is detected at an early stage, it can often be removed by surgery. In some cases, however, the cancer spreads to other parts of the body, making surgery impossible. This stage of the disease is called metastatic colorectal cancer. Metastatic colorectal cancer is not curable. However, several drugs exist which can prolong the life of patients. These drugs are known as chemotherapeutic agents, and they use different ways of stopping cancer cells from growing.

Trifluridine/tipiracil is one such chemotherapeutic agent. It enters the cancer cells and makes it more difficult for them to grow. Trifluridine/tipiracil is used in patients, in whom other drugs which are also available for the treatment of metastatic colorectal cancer, did not work or stopped working.

This study consisted of two groups: patients who were treated with trifluridine/tipiracil and patients who received best supportive care. Best supportive care means that patients receive treatments to reduce their symptoms (such as pain), but no therapy to fight their cancer. Patients were allowed to chose which treatment they would like to receive.

The main objective of this study was to look at the quality of life of patients under the treatment of trifluridine/tipiracil.

2 When and where did this study take place?

When did the study take place?

- This study started in September 2017.
- It ended in December 2020.

Where did the study take place?

The study took place in Germany.

3 Who participated in the study?

Which participants were included in the study?

To take part, participants had to:

- be at least 18 years of age,
- have the diagnosis of metastatic colorectal cancer,
- have good organ function,
- have already received other therapies available for metastatic colorectal cancer (unless the patients were not suitable for these therapies).

Patients could not participate in this study, if they:

- had already been treated with trifluridine/tipiracil before,
- had another type of cancer or severe disease in addition to colorectal cancer.

How many participants took part in the study?

A total of 195 participants took part in the study: 73 women and 122 men.

How old were the participants?

The average age of the participants was 66.5 years. The youngest participant was 40 years old and the oldest was 88 years old.

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4 Which treatments did the participants receive?

Participants received either trifluridine/tipiracil or best supportive care.

- Trifluridine/Tipiracil:

  Trifluridine/tipiracil was given orally as film tablets at a dosage of 35 milligrams per square meter of body surface area, twice daily. Thus, the total daily dose was 70 milligrams per square meter of body surface area.

  The participants took trifluridine/tipiracil during time periods called "cycles". One cycle lasted 28 days. The drug was given on days 1-5 and on days 8-12 of each cycle.

  These 28-day cycles were repeated for as long as the cancer did not progress and the participant did not have too severe side effects. The participant could also decide to stop the treatment at any time.

- Best supportive care:

  Participants received treatments to reduce their symptoms (such as pain) and improve their quality of life. Participants did not receive any therapy to fight their cancer.

5 How was the study carried out?

Participants were allowed to chose between the two treatments.

Among the 202 participants included in the study,
- 186 participants received trifluridine/tipiracil,
- 9 participants received best supportive care,
- 7 participants stopped the study before receiving the treatment.

The study is called an "open-label" study. This means that both the participants and the research doctors knew which treatment was taken.

The participants visited the doctors regularly at the start of each therapy cycle. During the visits, the patients received a new prescription for the study drug, as well as a diary to document drug intake.

6 What were the side effects?

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

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

	Trifluridine/tipiracil (out of 185 participants)	Best supportive care (out of 9 participants)
Participants who had side effect(s)	179 (96.2%)	7 (77.8%)
Participants who had serious* side effect(s)	83 (44.6%)	5 (55.6%)
Participants who stopped the treatment because of side effect(s)	53 (28.5%)	Not applicable

= participants

**See definition of serious side effects below*

The safety of trifluridine/tipiracil therapy is comparable to best supportive care.

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What were the side effects?

The table below shows the most common side effects reported in the study (reported by at least 5% of participants*).

	Trifluridine/tipiracil (out of 186 participants)	Best supportive care (out of 9 participants)
Low neutrophil count (a white blood cell type)	55 (29.6%)	0 (0%)
Low red blood cell count	46 (24.7%)	1 (11.1%)
Tiredness	43 (23.1%)	2 (22.2%)
Sickness	44 (23.7%)	1 (11.1%)
Diarrhoea	40 (21.5%)	0 (0%)
Low white blood cell count	37 (19.9%)	0 (0%)
Decreased appetite	26 (14.1%)	0 (0%)
Cancer progression	25 (13.5%)	1 (11.1%)
Vomiting	28 (15.1%)	1 (11.1%)
Constipation	22 (11.8%)	0 (0%)
Difficulty breathing	19 (10.2%)	0 (0%)
Swelling, fluid retention	19 (10.2%)	0 (0%)
Fever	17 (9.1%)	0 (0%)
Abdominal pain	13 (7.0%)	1 (11.1%)
Hair loss	13 (7.0%)	0 (0%)
Fluid in the abdomen	10 (5.4%)	1 (11.1%)
Pain	9 (4.8%)	2 (22.2%)
General physical health deterioration	11 (5.9%)	1 (11.1%)
Infection	9 (4.4%)	1 (11.1%)
Damage of multiple peripheral nerves	11 (5.9%)	0 (0%)

What were the serious side effects?

A 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.

The table below shows the most common serious side effects reported in the study (reported by at least 2% of participants).

	Trifluridine/tipiracil (out of 186 participants)	Best supportive care (out of 9 participants)
Cancer progression	23 (12.4%)	1 (11.1%)
Low red blood cell count	4 (2.2%)	0 (0%)
Inflammation of the bile duct	4 (2.2%)	0 (0%)
Reduction or blockade of bile flow	5 (2.7%)	0 (0%)
General physical health deterioration	4 (2.2%)	0 (0%)
Vomiting	4 (2.2%)	0 (0%)
Acute kidney injury	4 (2.2%)	1 (11.1%)
Infection	3 (1.6%)	1 (11.1%)

In the study, 26 participants died because of an unwanted event. Among the 25 participants,

- 25 participants received trifluridine/tipiracil.
- 1 participant received best supportive care.
- no death was thought to be related to trifluridine/tipiracil treatment.
- 24 deaths were thought to be related to cancer Progression.

7 What were the study results?

The study was completed as planned.

This document presents only the results for the main goal of the study. Other results are available in other documents listed in section 10.

The main goal of this study was to assess the quality of life of patients with metastatic colorectal cancer under the treatment of trifluridine/tipiracil or best supportive care.

Quality of life was assessed as follows:

- Participants had to fill in a questionnaire before the start of the therapy and within 2 days before, or on the first day of every therapy cycle.
- The questionnaire included, amongst others, questions on the physical activity, emotional health, social life, and symptoms such as pain or sickness.
- The quality of life before start of the therapy was compared to the quality of life during the therapy.

The table below shows the number of participants in whom the quality of life remained unchanged or improved during the therapy.

	Trifluridine/tipiracil (out of 106* participants)	Best supportive care (out of 6* participants)
Participants with unchanged or improved quality of life	62 (58.5%)	3 (50%)

= participants

*Since not all participants filled in the questionnaires, the number of participants differs from the total number of participants who were included in the study.

8 How has this study helped research?

The study found that:

- Patients with metastatic colorectal cancer maintain their quality of life during trifluridine/tipiracil therapy.
- Trifluridine/tipiracil therapy has an acceptable safety profile.
- Most of the participants chose trifluridine/tipiracil therapy.
- Trifluridine/tipiracil is a treatment option for patients with metastatic colorectal cancer.

The most important limitation of this study is:

- The number of participants receiving best supportive care was very low. Therefore, differences between the two treatment groups should be interpreted with caution.

This summary shows only the main results from this one study. Other studies, evaluating the same drug, may find different results.

9 Are there plans for further studies?

Clinical studies with trifluridine/tipiracil are on-going and further studies are planned.

Examples of on-going studies with trifluridine/tipiracil in metastatic colorectal cancer patients, indicated by their clinical trial identifier:

- NCT05007132
- NCT03869892
- NCT04737187

10 Further information

What are the identification numbers of the study?

- Protocol code: Tallisur
- EudraCT number: 2017-000292-83
- ISRCTN Code: ISRCTN90009147

Who did the study?

The company that organised and funded the research, called the "sponsor", is SERVIER Deutschland GmbH based in Munich, Germany.

How can you contact the sponsor?

Contact us on the Servier website: https://servier.com/en/ & *https://www.servier.de/*

Where can you learn more about this study?

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

- https://clinicaltrials.servier.com/trial/prospective-multicenter-open-label-phase-iv-trial-of-trifluridinetipiracil-to-evaluate-the-health-related-quality-of-life-in-patients-with-metastatic-colorectal-cancer/
- https://www.clinicaltrialsregister.eu/ctr-search/trial/2017-000292-83/DE

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/