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Trial record **1 of 1** for: NCT03258021

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TTFields In GERMANY in Routine Clinical Care (TIGER)

This study is currently recruiting participants.

See [▶ Contacts and Locations](#)

Verified September 2017 by NovoCure Ltd.

Sponsor:


NovoCure Ltd.

ClinicalTrials.gov Identifier:

NCT03258021

First Posted: August 22, 2017

Last Update Posted: September 13, 2017

 The safety and scientific validity of this study is the responsibility of the study sponsor and investigators. Listing a study does not mean it has been evaluated by the U.S. Federal Government. [Know the risks and potential benefits](#) of clinical studies and talk to your health care provider before participating. Read our [disclaimer](#) for details.

Information provided by (Responsible Party):

NovoCure Ltd.

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[▶ Purpose](#)

The purpose of this post-authorisation medical device study is to obtain real life data on the use of tumor-treating fields (TTFields) in patients with newly diagnosed GBM in routine clinical care in Germany.

Patients with newly diagnosed GBM and clinical indication for TTFields treatment will be enrolled in the study after signing Informed consent to use their data and process it centrally for research purposes. The

clinical indication for TTFields is one of the inclusion criteria and is defined prior to inclusion by the treating physician. The patient's decision regarding TTFields treatment is part of the observation and will be assessed within the baseline visit.

<u>Condition</u>	<u>Intervention</u>
Glioblastoma	Device: TTFields

Study Type: Observational

Study Design: Observational Model: Other

Time Perspective: Prospective

Official Title: The Use of TTFields for Newly Diagnosed GBM Patients in Germany in Routine Clinical Care - TIGER Study

Resource links provided by NLM:

[Genetic and Rare Diseases Information Center](#) resources: [Glioblastoma](#) [Glioma](#)
[Neuroepithelioma](#)

[U.S. FDA Resources](#)

Further study details as provided by NovoCure Ltd.:

Primary Outcome Measures:

- Time to death of any cause (overall survival (OS)) from diagnosis [Time Frame: through study completion, an average of 18 months (mean FU time)]

Time to death of any cause (overall survival (OS)) from diagnosis is measured using the patient data from date of enrollment until the date of death from any cause

- Number of TTFields treatment-related serious adverse events (SAEs) standardized to one year of FU time [Time Frame: through study completion, an average of 18 months (mean follow-up time)]

Number of TTFields treatment-related SAEs standardized to one year of follow-up (FU) is measured using the collection of SAEs during the follow-up period

- Number of SAEs after start of TTFields treatment [Time Frame: through study completion, an average of 18 months (mean follow-up time)]

Number of SAEs after start of TTFields treatment is measured using the collection of SAEs at the follow-up period

- Time of usage (compliance) of TTFields treatment over time [Time Frame: through study completion, an average of 18 months (mean follow-up time)]

Time of usage (compliance) of TTFields treatment over time is measured using the treatment compliance report at the Follow-up period

- Time to first progression of GBM (progression-free survival (PFS)), defined within radiological and/or clinical/neurological assessment during routine clinical care in patients who started TTFields treatment at baseline [Time Frame: through study completion, an average of 18 months (mean follow-up time)]

Time to first progression of GBM (progression-free survival (PFS)), defined within radiological and/or clinical/neurological assessment during routine clinical care in patients who started TTFields treatment at baseline from date of enrollment until the date of first progression of GBM

- Changes in quality of life at month 2 and month 4 after start of TTFields treatment compared to baseline in patients who started TTFields treatment at baseline [Time Frame: month 2 and month 4 after start of TTFields treatment compared to baseline in patients who started TTFields treatment at baseline]

Changes in quality of life assessed via questionnaires EORTC Quality of life questionnaires (QLQ) QLQ-C30 and BN20 after start of TTFields treatment compared to baseline in patients who started TTFields treatment at baseline is measured using the QoL questionnaires at months two and four after start of TTFields treatment

- Patients' reason(s) for refusing TTFields at baseline [Time Frame: baseline]

Patients' reason(s) for refusing TTFields is measured using a study specific questionnaire at baseline

Estimated Enrollment:	1000
Actual Study Start Date:	August 31, 2017
Estimated Study Completion Date:	March 2020
Estimated Primary Completion Date:	February 2020 (Final data collection date for primary outcome measure)

[Groups/Cohorts](#)

[Assigned Interventions](#)

<p>GBM with indication for TTFields</p> <p>newly diagnosed GBM with clinical indication for TTFields</p>	<p>Device: TTFields</p> <p>Tumor treating fields (TTFields) help slow down or stop glioblastoma cancer cells from dividing by disrupting dividing mechanism of cancer cells leading to apoptosis. TTFields are low-intensity, intermediate frequency, alternating electric fields delivered continuously through adhesive patches, called transducer arrays, to the area of the brain where the GBM tumor is located. These transducer arrays are applied to the scalp and are connected to the wearable and portable device. TTFields are approved for the treatment of newly diagnosed and recurrent GBM.</p>
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Detailed Description:

Glioblastoma (GBM) is the most common malignant primary tumor of the brain. The current standard of care for patients with newly diagnosed GBM consists of maximal surgical resection, approx. 60 Gy of radiotherapy together with chemotherapy using temozolomide (TMZ), followed by maintenance TMZ for 6 months. This treatment scheme was shown to extend median survival from 12.1 to 14.6 months compared to surgery and radiotherapy alone. This survival was essentially unchanged since 2005 despite numerous clinical Phase 3 trials conducted.

Although immense efforts were made over the years with different treatment strategies, the survival of patients with newly diagnosed GBM remained very poor until recently. Tumor-treating fields (TTFields) are low-intensity, intermediate frequency, alternating electric fields delivered continuously through adhesive patches, called transducer arrays, to the area of the brain where the GBM tumor is located and help slow down or stop glioblastoma cancer cells from dividing. These transducer arrays are applied to the scalp and are connected to the wearable and portable device.

TTFields are the first treatment since 2005 to demonstrate significantly extended median overall survival and significantly improved long-term survival (one to five year survival rates) compared to the current standard of care. In addition, TTFields significantly extended progression-free survival.

In the Phase 3 trial in newly diagnosed GBM (trial EF-14) the results demonstrated that the addition of TTFields to maintenance TMZ significantly extends both, median and long term survival, as well as progression free survival of patients with newly diagnosed GBM. The magnitude of survival benefit seen is even better to that seen for addition of TMZ to radiation, which established TMZ as the standard of care for 1st line GBM treatment in 2005. Quality of life (QoL) was maintained with the use of TTFields + TMZ in patients for whom 12 months of QoL data were available. The addition of TTFields to TMZ therapy in patients with newly diagnosed glioblastoma was not associated with any significant increase in systemic toxic effects compared with TMZ therapy alone. The most commonly reported side effect from the delivery of TTFields was a mild-to-moderate skin irritation beneath the transducer arrays.

► Eligibility

Information from the National Library of Medicine



Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the contacts provided below. For general information, [Learn About Clinical Studies](#).

Ages Eligible for Study: 18 Years and older (Adult, Senior)
Sexes Eligible for Study: All
Accepts Healthy Volunteers: No
Sampling Method: Non-Probability Sample

Study Population

Patients with newly diagnosed GBM with clinical indication for TTFields treatment, as indicated by the treating physician, will be included in the study, provided all inclusion and no exclusion criteria are met and written consent is given to use and process their routine clinical data according to data privacy standards.

Criteria

Inclusion Criteria:

- Newly diagnosed histologically confirmed GBM (WHO-Grade IV)
- Patient within first 3 cycles of first-line tumor-specific maintenance chemotherapy
- ≥ 18 years of age
- Clinical indication for TTFields treatment
- Given informed consent for use and processing of data

Exclusion Criteria:

- Present or planned pregnancy
- Significant additional neurological disease (e.g. significantly increased intracerebral pressure (ICP) with a significant midline shift of the brain)
- Active implanted medical device (e.g. deep brain stimulator)
- Documented allergy to conductive hydrogel
- Skull defect (e.g. missing bone with no replacement, bullet fragments in the skull)

▶ Contacts and Locations

Information from the National Library of Medicine



To learn more about this study, you or your doctor may contact the study research staff using the contact information provided by the sponsor.

Please refer to this study by its ClinicalTrials.gov identifier (NCT number):
NCT03258021

Contacts

Contact: Frieda Zweynert +49 89 990 1649 968 tiger@cri-muc.eu

Locations

Germany

University Hospital Frankfurt **Recruiting**

Frankfurt am Main, Germany, 60528

Contact: Oliver Bähr, Dr

Sponsors and Collaborators

NovoCure Ltd.

Investigators

Principal Investigator: Oliver Bähr, Dr. University Hospital Frankfurt, Frankfurt am Main, Germ



▶ More Information

Publications:

[Dolecek TA, Propp JM, Stroup NE, Kruchko C. CBTRUS statistical report: primary brain and central nervous system tumors diagnosed in the United States in 2005-2009. Neuro Oncol. 2012 Nov;14 Suppl 5:v1-49. doi: 10.1093/neuonc/nos218. Review. Erratum in: Neuro Oncol. 2013 May;15\(5\):646-7.](#)

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Individual Participant Data (IPD) Sharing Statement:

Plan to Share IPD: No

Studies a U.S. FDA-regulated Drug Product: No
Studies a U.S. FDA-regulated Device Product: Yes
Device Product Not Approved or Cleared by U.S. FDA: No
Product Manufactured in and Exported from the U.S.: No

Keywords provided by NovoCure Ltd.:

Glioblastoma
GBM
Tumor-treating fields
TTFields

Additional relevant MeSH terms:

Glioblastoma	Neoplasms, Germ Cell and Embryonal
Astrocytoma	Neoplasms by Histologic Type
Glioma	Neoplasms
Neoplasms, Neuroepithelial	Neoplasms, Glandular and Epithelial
Neuroectodermal Tumors	Neoplasms, Nerve Tissue

