Trial Description

Title

PROSPECTIVE OBSERVATIONAL STUDY ON THE UTILISATION AND TREATMENT RESULTS OF PATIENTS NEWLY TREATED WITH DROPIZOL® (OPIUM TINCTURE) UNDER CONDITIONS OF EVERYDAY PRACTICE

Trial Acronym

CLARIFY DROPIZOL®

URL of the trial

[---]*

Brief Summary in Lay Language

Patients with severe diarrhoea are common in clinical practice. Patients with chemotherapy, radiotherapy, chronic inflammatory bowel disease, ileostoma or short bowel syndrome are particularly affected. Loperamide and opium tincture if other measures have not been effective, are approved for therapy in Germany. Since the end of 2018, the latter has also been available as a finished drug under the name Dropizol, which simplifies its use. Although discontinued opium tincture has been used to treat diarrhea for more than 100 years, there is no data in the scientific literature from studies on the success of clinical use.

The CLARIFY-DROPIZOL study will close this gap. It was planned to systematically collect data from about 250 patients in 15 practices and clinics from Q2 2019 to Q1 2020 (update in 12/2020: reduction of the number of patients to about 80 due to Covid-19 restrictions, extension of the documentation period until Q1 2021) for a maximum period of 6 months per patient (for oncological patients, until the current therapy regimen changes). Data are systematically collected from patients with severe diarrhoea who are treated with Dropizol. This includes the dosage, the effect of the preparation on diarrhoea, the time to effect, quality of life and side effects. Such data have not yet been collected in clinical practice.

Brief Summary in Scientific Language

Non-interventional study on utilisation, effectiveness, tolerability, and quality of life in patients with severe diarrhea who are newly treated with Dropizol within the indication of this finished product. The study was designed to be interdisciplinary, and patients with various underlying conditions associated with severe diarrhea can be documented.

Do you plan to share individual participant data with other researchers?

No

Description IPD sharing plan

[---]*

Organizational Data

- DRKS-ID: **DRKS00017294**
- Date of Registration in DRKS: **2019/05/13**
- Date of Registration in Partner Registry or other Primary Registry: **[---]***
- Investigator Sponsored/Initiated Trial (IST/IIT): **no**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **F-2019-042 , Ethik-Kommission bei der Landesärztekammer Baden-Württemberg**

Secondary IDs

Health condition or Problem studied

- Free text: **Severe diarrhea**
- ICD10: **K52 - Other noninfective gastroenteritis and colitis**

Interventions/Observational Groups

- Arm 1: **Patients with servere diarrhea who are newly treated with Dropizol(R)**

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Observational study**
- Allocation: **Single arm study**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Uncontrolled/Single arm**
- Purpose: **Treatment**
- Assignment: **Single (group)**
- Phase: **IV**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **No**

Primary Outcome

• Change in number of stools per day at approximately 10 days compared to baseline (treatment initiation)
• Ileostomy patients: change in excretion quantity (ml) in bag at approximately 10days compared to baseline (treatment initiation)
• Dropizol® dosage at approximately 10-14 days compared to baseline

Secondary Outcome

Change in number of stools per day at 6 months (or end of observation) compared to baseline (treatment initiation)
• In ileostomy patients: change in excretion quantity (ml) in bag at end of observation compared to baseline
o at reversal of ileostoma
o at introduction of new line of chemotherapy (adjuvant therapy)
o in any case no later than 6 months
• Dropizol® dosage at 6 months (or end of observation) compared to baseline (treatment initiation)
• Time to effect (= days of Dropizol® treatment leading to normalized frequency of stools per day)
• Dosing pattern (number of Dropizol® doses per day)
• In oncological patients only: STIDAT total score at 6 months (or end of observation) compared to baseline (treatment initiation)
• QoL (by EQ-5D VAS) at 6 months (or end of observation) compared to baseline (treatment initiation)
• QLQ-C30 at 6 months (or end of observation) compared to baseline (treatment initiation)

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- Medical Center **Darmzentrum, St. Elisabethen-Klinikum, Ravensburg**
- Medical Center **Norddeutsches Studienzentrum für Innovative Onkologie GbR, Hamburg**
- Medical Center **Theresienkrankenhaus (Allgemein- und Viszeralchirurgie) , Mannheim**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2019/09/06**
- Target Sample Size: **80**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

• Severe diarrhoea, e.g. diarrhoea caused by cytostatic drugs, radiation or neuroendocrine tumours, if the application of other antidiarrheal drugs has not produced a sufficient effect.
• Written consent before the first documentation.
• Newly treated with Dropizol® within the provisions of the Summary of Product Characteristics (SPC)

Exclusion criteria

• Contraindications as described in the Summary of Product Characteristics
• Lack of cognitive and linguistic ability to participate in the study
• Patient (probably) not available for follow-up period (up to 6 months)
• Pregnancy

Addresses

- **Primary Sponsor**

  GWT-TUD GmbH, Medizin
  Ms. Doris Breiner
  Freiberger Str. 33
  01067 Dresden
  Germany

  Telephone: **0351 259 33182**
  Fax: **[---]***
  E-mail: **doris.breiner at gwtonline.de**
  URL: **http://gwtonline.de**

- **Contact for Scientific Queries**

  GWT-TUD GmbH
  Mr. Prof. Dr. David Pittrow
  Freiberger Str. 33
  01067 Dresden
  Germany

  Telephone: **0351 25933182**
  Fax: **[---]***
  E-mail: **david.pittrow at mailbox.tu-dresden.de**
  URL: **http://gwtonline.de**

- **Contact for Public Queries**

GWT-TUD GmbH, Medizin
Ms. Doris Breiner
Freiberger Str. 33
01067 Dresden
Germany

Telephone: **0351 259 33184**
Fax: **[---]***
E-mail: **doris.breiner at gwtonline.de**
URL: **http://gwtonline.de**

- **Collaborator, Other Address**

InnoCur Pharma GmbH
Mr. Dr. Giuseppe Gianni
Hanauer Landstr. 146
60314 Frankfurt am Main
Germany

Telephone: **+49 (0) 69 400 55 36 00**
Fax: **[---]***
E-mail: **info at innocur.de**
URL: **[---]***

Sources of Monetary or Material Support

- **Commercial (pharmaceutical industry, medical engineering industry, etc.)**

InnoCur Pharma GmbH
Hanauer Landstr. 146
60314 Frankfurt am Main
Germany

Telephone: **+49 (0) 69 400 55 36 00**
Fax: **[---]***
E-mail: **[---]***
URL: **www.innocur.de**

Status

- Recruitment Status: **Recruiting ongoing**
- Reason, if "Recruitment stopped after recruiting started" or "Recruiting withdrawn before recruting started": **[---]***
- Reason, if Reason for Recruiting Stop "Other": **[---]***
- Study Closing (LPLV): **[---]***

- Number of Participants in Germany after Recruiting complete: **[---]***
- Total Number of Participants (all Sites worldwide) after Recruiting complete: **[---]***

Trial Publications, Results and other documents

** This entry means the parameter is not applicable or has not been set.*

**** This entry means that data is not displayed due to insufficient data privacy clearing.*