Intravenous Ferric Carboxymaltose vs. Oral Iron Substitution in Patients With Metastatic Colorectal Cancer (CRC) and Iron Deficiency Anemia: a Randomized Multicenter Treatment Optimization Study.

This study is currently recruiting participants. (see Contacts and Locations)

Verified June 2015 by Krankenhaus Nordwest

Sponsor:
Krankenhaus Nordwest

Information provided by (Responsible Party):
Krankenhaus Nordwest

ClinicalTrials.gov Identifier:
NCT02469480

First received: May 13, 2015
Last updated: June 11, 2015
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History of Changes

Purpose

Iron deficiency has a high prevalence in colorectal cancer patients ranging at ca. 60%. About 70% of these patients suffer from iron deficiency anemia (IDA) which adds both physical and cognitive impediments to an already straining chemotherapy. Moreover, a chronic disease like cancer often results in a reduced availability of iron for the body. In clinical practice iron substitution is usually administered orally. Due to low resorption rates, frequent gastric side effects and thus poor patient compliance a parenteral substitution seems to be a better option in terms of efficacy. In the framework of a randomized multicenter clinical trial (**'FerInject'**) a comparison of efficacy parameters of parenteral vs. oral iron substitution will now be conducted in order to identify the best treatment form for clinical practice in oncology. Furthermore detailed quality of life-data (QoL) will be collected in both treatment arms for effect comparison.

Condition	Intervention	Phase
Metastatic Colorectal Cancer	Drug: **FerInject** Drug: Ferro sanol	Phase 2

Study Type: Interventional
Study Design: Allocation: Randomized
Endpoint Classification: Efficacy Study
Intervention Model: Parallel Assignment
Masking: Open Label
Primary Purpose: Supportive Care

Official Title: Intravenous Ferric Carboxymaltose vs. Oral Iron Substitution in Patients With Metastatic Colorectal Cancer (CRC) and Iron Deficiency Anemia: a Randomized Multicenter Treatment Optimization Study.

Resource links provided by NLM:

MedlinePlus related topics: Anemia Cancer Colorectal Cancer Iron

Drug Information available for: Ferric carboxymaltose

U.S. FDA Resources

Further study details as provided by Krankenhaus Nordwest:

Primary Outcome Measures:

- Rise or normalization of hemoglobin [Time Frame: 12 weeks] [Designated as safety issue: No]

Secondary Outcome Measures:

- Fatigue as measured by EORTC-QLQ-FA13 [Time Frame: 12 w eeks] [Designated as safety issue: No]
- Quality of life as measured by EORTC-C30 [Time Frame: 12 w eeks] [Designated as safety issue: No]
- Handgrip strength as measured by Hydraulic Hand Dynamometer [Time Frame: 12 w eeks] [Designated as safety issue: No]
- Number of allogenic blood transfusions (in total and per patient) [Time Frame: 12 w eeks] [Designated as safety issue: No]
- Time until rise or normalisation of hemoglobin [Time Frame: 12 w eeks] [Designated as safety issue: No]
- Genesis of the iron deficiency anemia [Time Frame: 12 w eeks] [Designated as safety issue: No]
- Number of therapy w ith recombinant erythropoietin [Time Frame: 12 w eeks] [Designated as safety issue: No]
- Dose of therapy w ith recombinant erythropoietin [Time Frame: 12 w eeks] [Designated as safety issue: No]
- Duration of therapy w ith recombinant erythropoietin [Time Frame: 12 w eeks] [Designated as safety issue: No]
- Inflammatory parameters [Time Frame: 12 w eeks] [Designated as safety issue: No]
- Influence nutritional status on iron deficiency anemia as measured by Nutritional Risk Screening (NRS 2002) [Time Frame: 12 w eeks] [Designated as safety issue: No]
- Influence nutritional status on therapy success as measured by Nutritional Risk Screening (NRS 2002) [Time Frame: 12 w eeks] [Designated as safety issue: No]
- Tolerance [Time Frame: 12 w eeks] [Designated as safety issue: No]
- Toxicity [Time Frame: 12 w eeks] [Designated as safety issue: No]
- Dropout rate due to toxicity or patient w ill [Time Frame: 12 w eeks] [Designated as safety issue: No]
- Overall survival [Time Frame: 12 w eeks] [Designated as safety issue: No]

Estimated Enrollment:	64
Study Start Date:	March 2015
Estimated Study Completion Date:	March 2017
Estimated Primary Completion Date:	September 2016 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: FERRIC CARBOXYMALTOSE max. 2.000 mg of ferric carboxymaltose over max. 2 w eeks (max. 1.000 mg per w eek).	Drug: **FerInject** **FerInject**: max. 2.000 mg of ferric carboxymaltose over max. 2 w eeks (max. 1.000 mg per w eek).
Active Comparator: ferro sanol(R) duodenal 100 mg 200 mg ferro sanol per day over 12 w eeks	Drug: Ferro sanol 200 mg ferro sanol per day over 12 w eeks

Eligibility

Ages Eligible for Study:	18 Years and older
Genders Eligible for Study:	Both
Accepts Healthy Volunteers:	No

Criteria

Inclusion Criteria:

1. Metastatic or inoperable colorectal carcinoma. No curative therapy available.
2. Current palliative chemotherapy. Patients under conversion therapy must not be enrolled to this study.
3. Iron deficiency anemia: hemoglobin ≤ 10.5 g/dl and transferrin saturation < 20 % and/or serum ferritin < 20 ng/ml
4. Male and female patients aged ≥ 18 years; maturity
5. ECOG ≤ 2
6. Written informed consent
7. Life expectancy > 6 months
8. Body w eight ≥ 40 kg

Exclusion Criteria:

1. Oral or intravenous iron substitution w ithin the last 4 w eeks
2. Age < 18 years or body w eight < 40 kg
3. Absorption dysfunction due to short bow el syndrome or after gastric resection
4. Therapy w ith recombinant erythropoietin w ithin the last 4 w eeks

5. Chronic diarrhea
6. Chronic inflammatory bow el disease
7. Ferritin > 800 mg/dl at baseline
8. Hypersensitivity or contraindication to ferric carboxymaltose or iron (II) glycine sulphate complex
9. Know n vitamin B12 or folic acid anemia
10. Necessary total parenteral nutrition
11. Participation in another interventional study
12. Pregnancy or lactation

Contacts and Locations

Choosing to participate in a study is an important personal decision. Talk w ith 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, see Learn About Clinical Studies.

Please refer to this study by its ClinicalTrials.gov identifier: NCT02469480

Contacts

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Sponsors and Collaborators

Krankenhaus Nordwest

More Information

Additional Information:

Related Info

No publications provided

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ClinicalTrials.gov Identifier:	NCT02469480 History of Changes
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Keywords provided by Krankenhaus Nordwest:
MCRC
iron substitution
iron deficiency anemia

Additional relevant MeSH terms:

Anemia	Iron Metabolism Disorders
Anemia, Iron-Deficiency	Malnutrition
Colorectal Neoplasms	Metabolic Diseases
Deficiency Diseases	Neoplasms
Anemia, Hypochromic	Neoplasms by Site
Colonic Diseases	Nutrition Disorders
Digestive System Diseases	Rectal Diseases
Digestive System Neoplasms	Ferric Compounds
Gastrointestinal Diseases	Hematinics
Gastrointestinal Neoplasms	Hematologic Agents
Hematologic Diseases	Pharmacologic Actions
Intestinal Diseases	Therapeutic Uses
Intestinal Neoplasms	

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