Randomised Clinical Trial Comparing Two Intravenous Iron Regimens in the Postoperative Period of Colorectal Cancer Surgery: Study Protocol

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INTRODUCTION
Prevalence of anaemia and/or iron deficiency in patients diagnosed of colorectal cancer (CRC) is > 50%. After surgery, this percentage increases to more than 80% due to intra and postoperative blood loss.

HYPOTHESIS
The single dose regimen of intravenous 1g of ferric carboxymaltose in the postoperative period is more effective than the fractional intravenous 200mg/48h iron sucrose regimen to normalize the haemoglobin (Hb) (13g/dL) at 30 days of surgery.

OBJECTIVE
To compare the effectiveness of 1g of ferric carboxymaltose against iron sucrose 200mg/48h for the postoperative anaemia by measuring the change of Hb levels from postoperative day 1 to day 30.

METHODS
We designed an OPEN LABEL RANDOMIZED CONTROLLED TRIAL to compare two postoperative IVI treatment regimens.

<table>
<thead>
<tr>
<th>Inclusion criteria</th>
<th>Exclusion criteria</th>
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<tbody>
<tr>
<td>&gt; 18 years old</td>
<td>Hb&gt;11g/dL on postoperative day 1</td>
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<tr>
<td>Colorectal cancer surgery</td>
<td>History of adverse effects to IVI</td>
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<tr>
<td>Hb&lt;11g/dL on postoperative day 1</td>
<td>ASA IV</td>
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<tr>
<td>Informed consent</td>
<td>Postoperative complications grade IV Clavien</td>
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</tbody>
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Main study variable | Change of Hb levels between postoperative day 1 and 30
Secondary variables | Number of transfusions
| Total iron dose received during the first 30 days
| Number of patients that normalize Hb levels
| Number of postoperative complications
| Changes in patient’s quality of live

SAMPLE: 48 patients per group will allow detecting a difference of 0.75 g/dL in the change in Hb levels from day 1 to day 30.

Inclusion patients started on September 2015
The end of recruitment is expected on September 2017

RESULTS: Recruitment status

Eligible patients 206
Informed consent 206
Surgery 206
Hb day 1 <11g/dL 61
Randomization 61

Stratum A: Hb<10 29
Stratum B: Hb≥10<11 32

1g IV ferric carboxymaltose 15
200mg/48h IV iron sucrose 14

1g IV ferric carboxymaltose 15
200mg/48h IV iron sucrose 14

CONCLUSIONS
A previous observational study showed that the prevalence of anaemia in CRC patients is high. An independent study to generate clinical evidence on the effectiveness of different postoperative IVI regimens is ongoing.

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