Patient Blood Management

NHS Blood and Transplant

# PREVENTT: A Summary of the Clinical Trial results webinar

5th September 2020

PREVENTT
Preoperative intravenous iron to treat anaemia in major surgery

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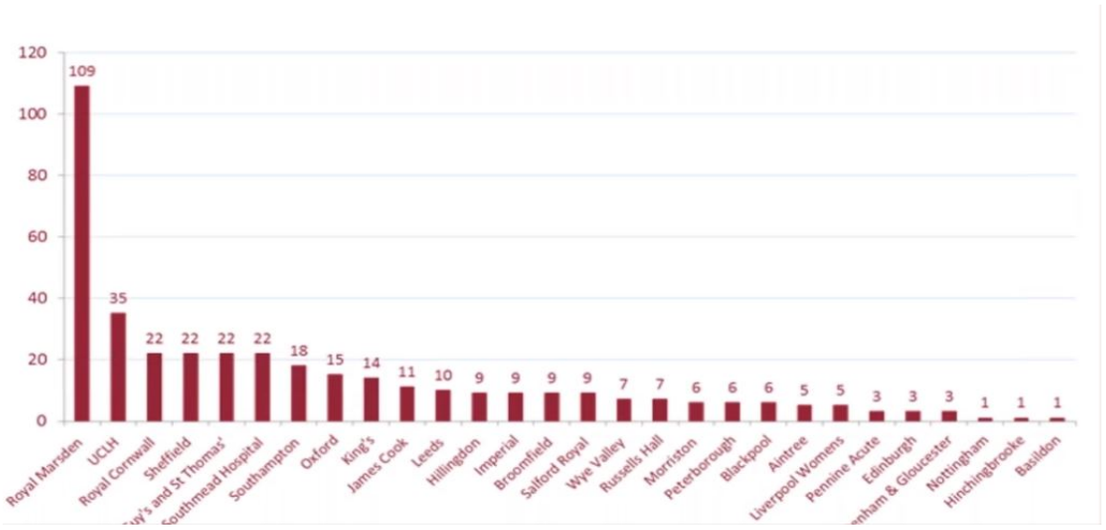
## Hypothesis

*Intravenous Iron will be superior to a placebo in respect to blood transfusion and death, adverse events and quality of life.*

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| **P** | Anaemia - M < 130 g/L, F <120 g/L. 10-42 days pre major abdominal surgery (BUPA definition | **I** | IV Iron 1000mg | **C** | Placebo - 100mls Saline (Double blind) | **O** | Risk of Transfusion or death, number of transfusion episodes - 30 days post op |

## Recruitment




**Challenges to recruitment:**

- Patients declining to attend for extra appointments on top of so many others
- Identifying patients with sufficient time to surgery
-Pre op service development in response to NICE Guidance (2015) publication

Royal Marsden attributed success to a "one stop shop" pre-op clinic and utilising IV iron services already established in their chemo centres and transfusion suites, as well as having a consultant lead pre-operative clinic to help streamline pathway.

Identifying patients at point of surgical clinic appointment promoted timely treatment

# Results

## Patient participation

487 Patients randomised
8 Withdrew
6 No intervention
23 No surgery
20 converted to non major surgery

Patient participated as per protocol: 388

## Comorbidities

Renal 16%
Respiratory 21%
Cardiac 10%
Diabetes 15%

**Randomisation- Placebo arm =243**
**- Treatment arm = 244**

**Average Pre- Op Hb for placebo and treatment group = 110 g/L**

**Average no of days' prior to Surgery intervention received = 14/15 days**

## Effect of IV Iron

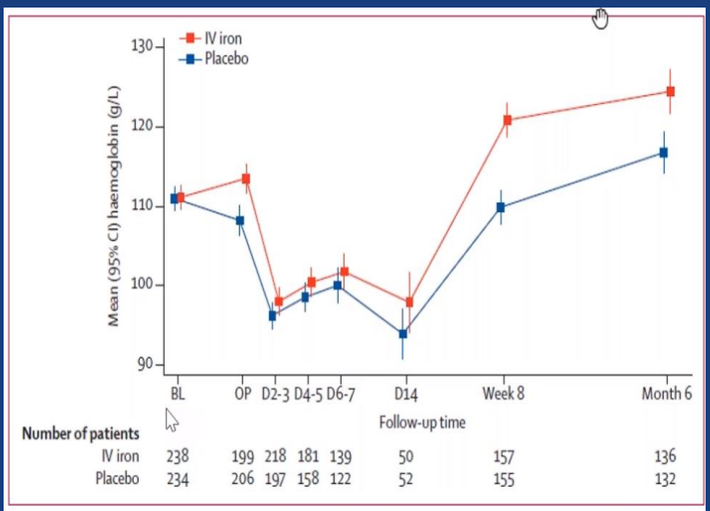



*Figure 2:* Mean haemoglobin concentrations of the trial participants by randomised treatment group

## Primary end points - Transfusion or death

| | Placebo (n=243) | Intravenous iron (n=244) | Iron vs placebo (95% CI, p value) |
|---|---|---|---|
| Blood transfusion or death | | | |
| Combined | 67/237 (28%) | 69/237 (29%) | 1·03 (0·78–1·37, p=0·84) |
| Transfusion | 67/237 (28%) | 68/237 (29%) | .. |
| Death | 2/237 (1%) | 2/237 (1%) | .. |
| Transfusion episodes | | | |
| 0 | 170/237 (72%) | 169/237 (71%) | .. |
| 1 | 37/237 (16%) | 49/237 (21%) | .. |
| 2 | 22/237 (9%) | 9/237 (4%) | .. |
| 3 | 5/237 (2%) | 5/237 (2%) | .. |
| 4 | 1/237 (<1%) | 3/237 (1%) | .. |
| 5 | 1/237 (<1%) | 1/237 (<1%) | .. |
| 6 | 1/237 (<1%) | 1/237 (<1%) | .. |
| Mean | 0·47 (0·9) | 0·44 (0·9) | 0·98 (0·68–1·43, p=0·93) |

**139 patients in total received transfusion (29%)**
**216 episodes of transfusion (3 platelet, 3 FFP)**

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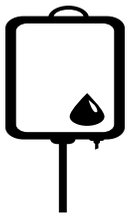
## Secondary outcomes

- No difference in average amount of blood given between placebo or treatment group
- No difference in adverse outcomes or length of stay between treatment and placebo groups
- No change in self reported Quality of Life in either group
- Less unplanned readmissions in the treatment group
  Lower prevalence of post op infection in treatment group

## Conclusion

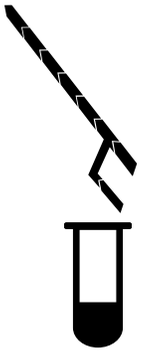
*PREVENTT showed that IV iron was not superior to placebo when administered to patients with anaemia 10-42 days before elective major abdominal surgery, with respect to blood transfusion or death in the perioperative period*

## Discussion points



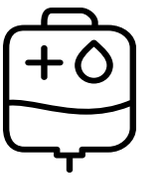
Dosing? Would calculated iron dosing based upon weight and Hb levels, or using a larger standard dose produce different outcomes.

Time to surgery - was a mean average of 15 days enough? Time frame reduced due to cancer pathway targets



Patient pathway- would other specialist pathways (non cancer related) see better results

Patients screened and treated based on anaemia rather than specifically the identification of Iron deficiency



Transfusion threshold- was recommended and questionnaires ensured they were routinely in place, but not enforced. No record of average pre tx Hb

Clinical judgement to transfuse will be affected by individual variation and disease/disorder

Royal Marsden feedback suggested they would continue to use IV iron where true Iron deficiency was present. IVICA follow up study (Dickson et al. 2020) found there may be long term benefits to correcting Iron deficiency

## Further reading

The article:
http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(20)31539-7/fulltext

The webinar
https://anaesthetists.org/Home/Education-events/Events/Event-Details/eventDateId/329

Discussion with CI Toby Richards
https://soundcloud.com/plenarysession/ep310