Call Toll-free 1-800 856-7842 or 828-254-0881 with Extension listed

Name of Study: A Phase III Safety Study of Ferumoxytol Compared to Ferric Carboxymaltose for the Treatment of Iron Deficiency Anemia (FIRM)-(AMAG Pharmaceuticals)

Link: https://clinicaltrials.gov/ct2/show/NCT02694978?term=AMAG+iron+deficiency&rank=8

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Study Coordinator: Chris Childres x 3417 or Direct 828-255-2471

Enrollment Begins: June 2016

Enrollment Ends: Mar 2017

Summary: To evaluate the safety of 1.020 g of IV ferumoxytol compared to 1.500 g of IV Ferric Carboxymaltose (FCM).

Inclusion: Subjects with IDA and in whom intravenous iron treatment is indicated and defined as:

- Subjects with documented hemoglobin <12.0 g/dL for females and <14.0 g/dL for males within 60 days of dosing And
- Subjects with documented TSAT ≤20% or Ferritin ≤100 ng/mL within 60 days of dosing
- Documented history of unsatisfactory oral iron therapy or in whom oral iron cannot be tolerated, or for whom oral iron is considered medically inappropriate (as per oral iron history questionnaire)
- Subject is capable of understanding and complying with the protocol requirements and available for the duration of the study
- All subjects (male and female) of childbearing potential who are sexually active who agree to routinely use adequate contraception from randomization throughout the duration of the study

Exclusion:

- Known hypersensitivity reaction to any component of ferumoxytol or FCM

- History of allergy to an IV iron
- History of multiple drug allergies
- Subjects with dialysis dependent CKD
- Hemoglobin ≤7.0 g/dL
- Female subjects who are pregnant, intend to become pregnant, are breastfeeding, have a positive serum/urine pregnancy test or not willing to use effective contraceptive precautions during the study (including females of childbearing potential who are partners of male subjects)