Clinical Study Report: GlobiFer IBD

Draft 1.1

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10.1 Demographic and baseline tables

10.1.1 Patient disposition

10.1.1.1 Overview and study termination

All patients, n=22

	All patients		GlobiFer Forte		Ferrous sulphate	
	n	%	n	%	n	%
Patients randomised	22	100%	11	100%	11	100%
Patients randomized and treated	21	95,4%	11	100%	10	90,9%
Drop-outs prior/at end of the therapy phase	4	18,1%	2	18,1%	2	18,1%
AE	3	13,6%	0	0%	2	18,1%
Completers of therapy phase	18	81,8%	10	90,9%	9	81,8%
Drop-outs during the observation phase	1	4,5%	1	9,1%	0	0%
AE	1	4,5%	1	9,1%	0	0%
Completers of observation phase	17	77,2%	9	81,8%	9	81,8%

10.1.1.2 Number of patients per centre

All patients, n=22

	All patients		GlobiFer Forte		Ferrous sulphate	
Centres with screened patients	n	%	n	%	n	%
Patients randomised	22	100%	11	100%	11	100%
Queen Elizabeth Hospital						
Patients randomised	17	72,3%	8	72,7%	9	81,8%
Patients randomised and treated	16	94,1%	8	100%	8	88,8%
New Cross Hospital						
Patients randomised	5	22,7%	3	27,3%	2	18,2%
Patients randomised and treated	5	100%	3	100%	2	100%

10.1.1.3 Study termination

All patients, n=21

Study prematurely terminated	All patients		GlobiFer Forte		Ferrous sulphate	
	n	%	n	%	n	%
Yes	4	19%	2	18%	2	20%
No	17	81%	9	82%	8	80%
Total	21	100%	11	100%	10	100%
Reasons for premature study termination						
Adverse Event	2	100%	2	100%	2	100%

10.1.1.4 Study termination by study visit

Study examination: Week 4; All patients, n=21

Study prematurely terminated	All patients		GlobiFer Forte		Ferrous sulphate	
	n	%	n	%	n	%
Yes	1	5%	1	9%	0	0%
No	20	95%	10	91%	10	100%
Total	21	100%	11	100%	10	100%
Reasons for premature study termination						
Adverse Event	1	100%	1	100%	0	0%

Study examination: Week 12; All patients, n=21

Study prematurely terminated	All patients		GlobiFer Forte		Ferrous sulphate	
	n	%	n	%	n	%
Yes	2	10%	0	0%	2	20%
No	19	90%	11	100%	8	80%
Total	21	100%	11	100%	10	100%
Reasons for premature study termination						
Adverse Event	2	100%	0	0%	2	100%

Study examination: Week 24; All patients, n=21

Study prematurely terminated	All patients		GlobiFer Forte		Ferrous sulphate	
	n	%	n	%	n	%
Yes	1	5%	1	9%	0	0%
No	20	95%	10	91%	10	100%
Total	21	100%	11	100%	10	100%
Reasons for premature study termination						
Adverse Event	1	100%	1	100%	0	0%

10.1.1.5 Total study duration

All patients, n=21

Total study duration [days]	Arith. mean	SD	Minimum	Lower quartile	Median	Upper quartile	Maximum	n
All patients, n= 21	157	58	7	167	168	173	199	21
GlobiFer Forte	165	60	13	166	169	175	182	11
Ferrous sulphate	147	54	7	167	168	168	199	10

10.1.2 Protocol deviations

All patients, n=22

Assessment of deviation [major/minor] / Specification of deviation	All patients		GlobiFer Forte		Ferrous sulphate	
	n	%	n	%	n	%
Major or Minor						
Patients with protocol deviations	20	90,9%	11	100,0%	9	81,8%
Major						
Patients with protocol deviations	4	18,2%	2	18,2%	2	18,2%
Premature study termination before week 12	3	13,6%	1	9,1%	2	18,2%
Deviations from dosing schedule (>= 15%) for intake of the trial medication	3	13,6%	1	9,1%	2	18,2%
Minor						
Patients with protocol deviations	17	77,3%	10	90,9%	7	63,6%
Deviations from dosing schedule (<15%) for intake of the trial medication	11	50,0%	9	81,8%	2	18,2%
Final examination: day 168 ± 5 days after Day 0 (Date of Baseline)	4	18,2%	2	18,2%	2	18,2%
Telephone contact: day 14 ± 2 days after Day 0 (Date of Baseline)	3	13,6%	2	18,2%	1	9,1%
Control examination: day 28 ± 2 days after Day 0 (Date of Baseline)	2	9,1%	1	9,1%	1	9,1%
Control examination: day 84 ± 5 days after Day 0 (Date of Baseline)	2	9,1%	1	9,1%	1	9,1%
Screening visit: day -7 ± 4 days after Day 0 (Date of Baseline)	2	9,1%	1	9,1%	1	9,1%
Inclusion criteria: B12 and folate normal (CRF vs 2)	2	9,1%	1	9,1%	1	9,1%
Inclusion criteria: CDAI <150, CRP<10 or CAI score <4 (CRF vs 2)	2	9,1%	0	0,0%	2	18,2%
Patient randomised, but not enrolled (not eligible)	1	4,5%	0	0,0%	1	9,1%
Premature study termination after week 12	1	4,5%	1	9,1%	0	0,0%
Inclusion criteria: Establised inactive IBD (Chron's or UC) CRF vs 2	1	4,5%	0	0,0%	1	9,1%

10.1.3 Demographic data

10.1.3.1 Sex, race and age (categorized)

All patients, n=21

		All patients		GlobiFer Forte		Ferrous sulphate	
		n	%	n	%	n	%
Sex	Male	12	57,1%	6	54,5%	6	60,0%
	Female	9	42,9%	5	45,5%	4	40,0%
	Total	21	100,0%	11	100,0%	10	100,0%
Race	White	14	66,7%	6	54,5%	8	80,0%
	Black - African	1	4,8%	1	9,1%	0	0,0%
	Asian	5	23,8%	3	27,3%	2	20,0%
	Other	1	4,8%	1	9,1%	0	0,0%
	Total	21	100%	11	100%	10	100%
Age	16 – 29	9	42,9%	4	36,4%	5	50,0%
	30 – 39	3	14,3%	2	18,2%	1	10,0%
	40 – 49	1	4,8%	1	9,1%	0	0,0%
	50 - 59	5	23,8%	3	27,3%	2	20,0%
	>59	3	14,3%	1	9,1%	2	20,0%
	Total	21	100%	11	100%	10	100%

10.1.4 - 2 Demographic data - Age (descriptive statistics) and anthropometric data (for all patients and by sex) –

Kommentar [XP1]: Wollen wir das?

10.1.4 10.1.6: Alcohol drinking habits

All patients, n=21

	All patients		GlobiFer Forte		Ferrous sulphate	
	n	%	n	%	n	%
Non-drinker	10	47,6%	7	63,6%	3	30,0%
Drinker	11	52,4%	4	36,4%	7	70,0%
Total	21	100,0%	11	100,0%	10	100,0%

10.1.5 Smoking habits

All patients, n=21

	All patients		GlobiFer Forte		Ferrous sulphate	
	n	%	n	%	n	%
No smoker	19	90,5%	10	90,9%	9	90,0%
Smoker	2	9,5%	1	9,1%	1	10,0%
Total	21	100,0%	11	100,0%	10	100,0%

10.1.6 Vital signs at screening

All patients, n=21

Total study duration [days]	Arith. mean	SD	Minimum	Lower quartile	Median	Upper quartile	Maximum	n
Temperature [°C]								
All patients, n= 21	36,6	0,4	35,7	36,4	36,6	36,9	37,2	21,0
GlobiFer Forte	36,7	0,4	36,0	36,5	36,8	37,0	37,2	11,0
Ferrous sulphate	36,4	0,4	35,7	36,3	36,5	36,6	37,0	10,0
Blood pressure: systolic [mmHg]								
All patients, n= 21	119,3	16,8	90,0	107,0	114,0	130,0	173,0	21,0
GlobiFer Forte	117,8	19,0	103,0	108,0	110,0	118,0	173,0	11,0
Ferrous sulphate	118,0	15,8	90,0	104,8	118,5	131,8	139,0	10,0
Blood pressure: diastolic [mmHg]								
All patients, n= 21	68,3	10,4	54,0	60,0	67,0	75,0	95,0	20,0
GlobiFer Forte	69,5	12,2	56,0	58,0	68,0	75,5	95,0	11,0
Ferrous sulphate	66,0	7,3	54,0	60,8	65,0	68,8	79,0	10,0
Pulse [bpm]								
All patients, n= 21	78,0	15,2	52,0	67,0	79,0	89,0	105,0	21,0
GlobiFer Forte	80,5	17,5	52,0	69,0	88,0	92,5	105,0	11,0
Ferrous sulphate	74,2	10,6	60,0	67,3	71,5	81,3	94,0	10,0

10.1.7 Anamnestic data on Inflammatory Bowel Disease

All patients, n=21

	All patients		GlobiFer Forte		Ferrous sulphate	
	n	%	n	%	n	%
Colitis ulcerosa	15	71,4%	8	72,7%	7	70,0%
crohn's disease	6	28,6%	3	27,3%	3	30,0%
Total	21	100,0%	11	100,0%	10	100,0%

10.1.8 Medical history documented at screening

All patients, n=21;
Part 1/2 of table

	All patients		GlobiFer Forte		Ferrous sulphate	
	n	%	n	%	n	%
Skin: yes	6	29%	1	9%	5	50%
ongoing	4	67%	0	0%	4	80%
No	15	71%	10	91%	5	50%
Total	21	100%	11	100%	10	100%
Head, Eyes, Ears, Nose throat: yes	5	24%	2	18%	3	30%
ongoing	2	40%	2	100%	0	0%
No	16	76%	9	82%	7	70%
Total	21	100%	11	100%	10	100%
Respiratory: yes	5	24%	1	9%	4	40%
ongoing	3	60%	0	0%	3	75%
No	16	76%	10	91%	6	60%
Total	21	100%	11	100%	10	100%
Cardiovascular: yes	4	19%	2	18%	2	20%
ongoing	3	75%	2	100%	1	50%
No	17	81%	9	82%	8	80%
Total	21	100%	11	100%	10	100%
ongoing	4	19%	2	18%	2	20%
Gastrointestinal yes	21	100%	11	100%	10	100%
ongoing	20	95%	11	100%	9	90%
No	0	0%	0	0%	0	0%
Total	21	100%	11	100%	10	100%
Endocrine/Metabolic yes	5	24%	2	18%	3	30%
ongoing	5	100%	2	100%	3	100%
No	16	76%	9	82%	7	70%
Total	21	100%	11	100%	10	100%
Neurological yes	2	10%	2	18%	0	0%
ongoing		0%	2	100%	0	0%
No	19	90%	9	82%	10	100%
Total	21	100%	11	100%	10	100%

Part 2/2 of table

	All patients		GlobiFer Forte		Ferrous sulphate	
	n	%	n	%	n	%
Blood/Lymphatic						
yes	20	95%	10	91%	10	100%
ongoing	20	100%	10	100%	10	100%
No	1	5%	1	9%	0	0%
Total	21	100%	11	100%	10	100%
Musculoskeletal						
yes	2	10%	1	9%	1	11%
ongoing	1	50%	0	0%	1	100%
No	19	90%	10	91%	8	89%
Total	21	100%	11	100%	9	100%
Hepatic						
yes	0	0%	0	0%	0	0%
ongoing	0	0%	0	0%	0	0%
No	21	100%	11	100%	10	100%
Total	21	100%	11	100%	10	100%
Psychological/Psychiatric						
yes	0	0%	0	0%	0	0%
ongoing	0	0%	0	0%	0	0%
No	21	100%	11	100%	10	100%
Total	21	100%	11	100%	10	100%
Allergies						
yes	6	29%	2	18%	4	40%
ongoing	6	100%	2	100%	4	100%
No	15	71%	9	82%	6	60%
Total	21	100%	11	100%	10	100%
Surgery						
yes	7	33%	3	27%	4	40%
ongoing	3	43%	1	33%	2	50%
No	14	67%	8	73%	6	60%
Total	21	100%	11	100%	10	100%
Other						
yes	4	19%	4	36%	0	0%
ongoing	3	75%	3	75%	0	0%
No	17	81%	7	64%	10	100%
Total	21	100%	11	100%	10	100%

10.1.10 - 1 Concomitant diseases - Diseases documented at screening
10.1.10 - 2 Concomitant diseases - Changes throughout the study

Kommentar [XP2]: Das können wir so nicht erfassen, das die Medical history nur beim Screning erfasst wurde.

10.1.9 Concomitant medication

All patients, n=21;
Part 1/3 of table

Medication according to CRF records	All patients		GlobiFer Forte		Ferrous sulphate	
	n	%	n	%	n	%
Patients with remarks						
6 mercaptopurine	2	9,5%	1	9,1%	1	10,0%
acidophyllis	1	4,8%	0	0,0%	1	10,0%
adalimumab	1	4,8%	0	0,0%	1	10,0%
Adcal	1	4,8%	1	9,1%	0	0,0%
Adcal D3	3	14,3%	2	18,2%	1	10,0%
Adcal	4	19,0%	3	27,3%	1	10,0%
amitriptyline	1	4,8%	1	9,1%	0	0,0%
Amitriptyline hydrochloride	1	4,8%	0	0,0%	1	10,0%
amitriptyline	2	9,5%	1	9,1%	1	10,0%
Amlodipine	1	4,8%	1	9,1%	0	0,0%
Amoxicillin	2	9,5%	2	18,2%	0	0,0%
Asacol	4	19,0%	2	18,2%	2	20,0%
Asacol suppositories	1	4,8%	0	0,0%	1	10,0%
Azathioprine	5	23,8%	2	18,2%	3	30,0%
b12 injections	1	4,8%	1	9,1%	0	0,0%
Betahistine	1	4,8%	1	9,1%	0	0,0%
Betamethasone valerate scalp application 0.1%	1	4,8%	0	0,0%	1	10,0%
Bisoprolol	1	4,8%	0	0,0%	1	10,0%
Buccastem (prochlorperazine)	1	4,8%	1	9,1%	0	0,0%
Buscopan	1	4,8%	0	0,0%	1	10,0%
Calcium ergocalciferol	1	4,8%	0	0,0%	1	10,0%
Cetirizine	1	4,8%	0	0,0%	1	10,0%
Cilest	1	4,8%	1	9,1%	0	0,0%
Clenil modulite inhaler 100 mcg/actuation	1	4,8%	0	0,0%	1	10,0%
Clopidogrel	2	9,5%	1	9,1%	1	10,0%
Co-codamol 30/500	1	4,8%	0	0,0%	1	10,0%
Colchicine	1	4,8%	0	0,0%	1	10,0%
docusate sodium	1	4,8%	1	9,1%	0	0,0%
Domperidone	1	4,8%	1	9,1%	0	0,0%
doxycycline	1	4,8%	0	0,0%	1	10,0%
enoxaparin	1	4,8%	1	9,1%	0	0,0%
esomeprazole	1	4,8%	1	9,1%	0	0,0%
Felodipine/m/r	1	4,8%	0	0,0%	1	10,0%

Part 2/3 of table

Medication according to CRF records	All patients		GlobiFer Forte		Ferrous sulphate	
	n	%	n	%	n	%
Ferinject	1	4,8%	1	9,1%	0	0,0%
ferrous fumarate	1	4,8%	1	9,1%	0	0,0%
folic acid	3	14,3%	1	9,1%	2	20,0%
Hydrocortisone	2	9,5%	2	18,2%	0	0,0%
Hydrocortisone, iv steroids	1	4,8%	1	9,1%	0	0,0%
Hydrocortisone	3	14,3%	3	27,3%	0	0,0%
Ibuprofen	1	4,8%	0	0,0%	1	10,0%
infliximab	1	4,8%	1	9,1%	0	0,0%
Infliximab infusion	1	4,8%	1	9,1%	0	0,0%
inhaler salbutamol	1	4,8%	0	0,0%	1	10,0%
lactulose	1	4,8%	1	9,1%	0	0,0%
Lansoprazole	1	4,8%	1	9,1%	0	0,0%
Levothyroxine Sodium	1	4,8%	0	0,0%	1	10,0%
Levothyroxine	1	4,8%	0	0,0%	1	10,0%
Levothyroxine	1	4,8%	0	0,0%	1	10,0%
Lisinopril	1	4,8%	1	9,1%	0	0,0%
Loperamide	3	14,3%	1	9,1%	2	20,0%
Mercaptopurine	2	9,5%	1	9,1%	1	10,0%
Mercaptopurine (6 MP)	1	4,8%	0	0,0%	1	10,0%
Mercaptopurine	3	14,3%	1	9,1%	2	20,0%
Mesalazine	3	14,3%	2	18,2%	1	10,0%
Mesalazine m r 500 mg	1	4,8%	0	0,0%	1	10,0%
Mesalazine	4	19,0%	2	18,2%	2	20,0%
Mesren MR	1	4,8%	0	0,0%	1	10,0%
Metformin	2	9,5%	1	9,1%	1	10,0%
Methotrexat	1	4,8%	1	9,1%	0	0,0%
mezavant	2	9,5%	2	18,2%	0	0,0%
microgynon	1	4,8%	1	9,1%	0	0,0%
midazolam	1	4,8%	0	0,0%	1	10,0%
misoprostol	1	4,8%	1	9,1%	0	0,0%
Morphine	1	4,8%	1	9,1%	0	0,0%
moviprep	1	4,8%	0	0,0%	1	10,0%
Nexplanon	1	4,8%	1	9,1%	0	0,0%
Omeprazole	1	4,8%	1	9,1%	0	0,0%
oxytetracycline	1	4,8%	0	0,0%	1	10,0%
Paracetamol	4	19,0%	3	27,3%	1	10,0%
Paramax	1	4,8%	1	9,1%	0	0,0%

Part 3/3 of table

Medication according to CRF records	All patients		GlobiFer Forte		Ferrous sulphate	
	n	%	n	%	n	%
Pentasa (SR)	1	4,8%	1	9,1%	0	0,0%
pentasa suppositories (mesalazine)	1	4,8%	1	9,1%	0	0,0%
pentasa	5	23,8%	3	27,3%	2	20,0%
pentasa	7	33,3%	5	45,5%	2	20,0%
pethidine	1	4,8%	0	0,0%	1	10,0%
Phosphate enema	1	4,8%	1	9,1%	0	0,0%
Piriton	1	4,8%	1	9,1%	0	0,0%
Predfoam	2	9,5%	1	9,1%	1	10,0%
Prednisolone	5	23,8%	3	27,3%	2	20,0%
predsol retention enema	1	4,8%	1	9,1%	0	0,0%
quinine sulfate	1	4,8%	1	9,1%	0	0,0%
Quinine sulphate	1	4,8%	0	0,0%	1	10,0%
Quinine sulphate	2	9,5%	1	9,1%	1	10,0%
Ranitidine	1	4,8%	0	0,0%	1	10,0%
salofalk supp	1	4,8%	0	0,0%	1	10,0%
Senna	1	4,8%	1	9,1%	0	0,0%
Salamol easi-breathe actuated inhaler	1	4,8%	0	0,0%	1	10,0%
Symprove Live Activated Bacteria multi strain formula	1	4,8%	0	0,0%	1	10,0%
simvastin	1	4,8%	1	9,1%	0	0,0%
Simvastatin	2	9,5%	1	9,1%	1	10,0%
Simvastatin	3	14,3%	2	18,2%	1	10,0%
Temazepam	1	4,8%	1	9,1%	0	0,0%
thyroxine	1	4,8%	1	9,1%	0	0,0%
topical cream	1	4,8%	1	9,1%	0	0,0%
Trimethoprim	1	4,8%	0	0,0%	1	10,0%
ventolin	1	4,8%	0	0,0%	1	10,0%
Vitamin b12 injections	1	4,8%	0	0,0%	1	10,0%
Vitamin D	1	4,8%	1	9,1%	0	0,0%
vsl 3	1	4,8%	0	0,0%	1	10,0%
xylocaine	1	4,8%	0	0,0%	1	10,0%
Zinc	1	4,8%	0	0,0%	1	10,0%

Multiple entries per patient possible.

10.1.10 Study treatment - Calculated compliance acc. to drug accountability

All patients, n=21;

compliance to the trial medication	Arith. mean	SD	Minimum	Lower quartile	Median	Upper quartile	Maximum	n
All patients, n= 21	97%	4%	88%	93%	99%	100%	100%	17
GlobiFer Forte	95%	4%	88%	93%	96%	99%	100%	9
Ferrous sulphate	98%	3%	92%	92%	100%	99%	100%	8

10.2 Efficacy tables per protocol

10.2.1 Primary efficacy criteria:

10.2.1.1 Achievement a 1g/dl increase in haemoglobin over baseline at 12 weeks

n=17

	All patients		GlobiFer Forte		Ferrous sulphate	
	n	%	n	%	n	%
Achievement a 1g/dl increase in haemoglobin over baseline at 12 weeks	13	76%	5	56%	8	100%
No achievement a 1g/dl increase in haemoglobin over baseline at 12 weeks	4	24%	4	44%	0	0%
Total	17	100%	9	100%	8	100%

10.2.2 Secondary efficacy criteria

10.2.2.1 Sustainability of the 1g/dl increase in haemoglobin (baseline to 12 weeks) at week 24 achievement

n= 13

	All patients		GlobiFer Forte		Ferrous sulphate	
	n	%	n	%	n	%
Achievement a 1g/dl increase in haemoglobin over baseline at 24 weeks	12	92%	5	100%	7	88%
No achievement a 1g/dl increase in haemoglobin over baseline at 24 weeks	1	8%	0	0%	1	13%
Total	13	100%	5	100%	8	100%

10.2.2.2 Tolerance of study medication over baseline at 24 weeks

n= 13

	All patients		GlobiFer Forte		Ferrous sulphate	
	n	%	n	%	n	%
Patients with adverse events – possible related	3	14,3%	3	27,3%	0	0,0%
Patients without adverse events – possible related	18	85,7%	8	72,7%	10	100%
Total	21	100%	11	100%	10	100%
Patients with adverse events – probable related	3	14,3%	0	0,0%	3	30,0%
Patients without adverse events – probable related	18	85,7%	11	100%	7	70,0%
Total	21	100%	11	100%	10	100%

10.2.2.3 Secondary efficacy criteria – Adverse events over baseline at 24 weeks

n= 21

	All patients		GlobiFer Forte		Ferrous sulphate	
	n	%	n	%	n	%
Patients with adverse events	19	90,5%	11	100%	8	80,0%
Patients without adverse events	2	9,5%	0	0,0%	2	20,0%
Total	21	100%	11	100%	10	100%
Patients with adverse events – not related	16	76,2%	11	100%	5	50,0%
Patients without adverse events – not related	5	23,8%	0	0,0%	5	50,0%
Total	21	100%	11	100%	10	100%
Patients with adverse events – possible related	3	14,3%	3	27,3%	0	0,0%
Patients without adverse events – possible related	18	85,7%	8	72,7%	10	100%
Total	21	100%	11	100%	10	100%
Patients with adverse events – probable related	3	14,3%	0	0,0%	3	30,0%
Patients without adverse events – probable related	18	85,7%	11	100%	7	70,0%
Total	21	100%	11	100%	10	100%

10.2.2.4 Adherence over baseline at 12 weeks

n= 17

compliance to the trial medication	Arith. mean	SD	Minimum	Lower quartile	Median	Upper quartile	Maximum	n
All patients, n= 21	97%	4%	88%	93%	99%	100%	100%	17
GlobiFer Forte	95%	4%	88%	93%	96%	99%	100%	9
Ferrous sulphate	98%	3%	92%	92%	100%	99%	100%	8

10.2.2.5 Exacerbation of colitis ulcerosa over baseline at 12 weeks

n= 11

Changes of the CAI Score	Arith. mean	SD	Minimum	Lower quartile	Median	Upper quartile	Maximum	n
All patients, n= 21	-0,8	2,3	-7,0	-1,0	0,0	0,5	2,0	11,0
GlobiFer Forte	-0,7	3,0	-7,0	-0,8	0,5	1,0	2,0	6,0
Ferrous sulphate	-1,0	1,1	-3,0	-1,0	-1,0	0,0	0,0	5,0

10.2.2.6 Exacerbation of crohn's disease over baseline at 12 weeks

n= 4

Changes of the CDAI Score	Arith. mean	SD	Minimum	Lower quartile	Median	Upper quartile	Maximum	n
All patients, n=	-31,4	77,5	-98,0	42,5	-60,2	80,4	93,0	4,0
GlobiFer Forte	-10,0	78,7	-98,0	-61,5	-25,0	34,0	93,0	3,0
Ferrous sulphate	-81,2	14,2	-95,4	-88,3	-81,2	-74,1	-67,0	2,0

The 3rd patient of the ferrous sulphate group don't has a CDAI value for the week 12

10.2.2.7 Resolution of anaemia over baseline at 12 weeks

n= 17

Increase of haemoglobin [g/dl]	Arith. mean	SD	Minimum	Lower quartile	Median	Upper quartile	Maximum	n
All patients, n=	2,3	1,4	-0,3	1,2	2,5	3,6	4,0	17,0
GlobiFer Forte	1,5	1,3	-0,3	0,6	1,4	2,5	3,9	9,0
Ferrous sulphate	3,1	0,9	1,2	2,2	3,5	3,5	4,0	8,0

10.2.2.8 Effect on the colonic microbiota over baseline at 24 weeks

n= ??

Total study duration [days]	Arith. mean	SD	Minimum	Lower quartile	Median	Upper quartile	Maximum	n
All patients, n= 21								
GlobiFer Forte								
Ferrous sulphate								