Ferinject® in ND-CKD
An introduction

Vifor Pharma Ltd.
a company of the Galenica Group

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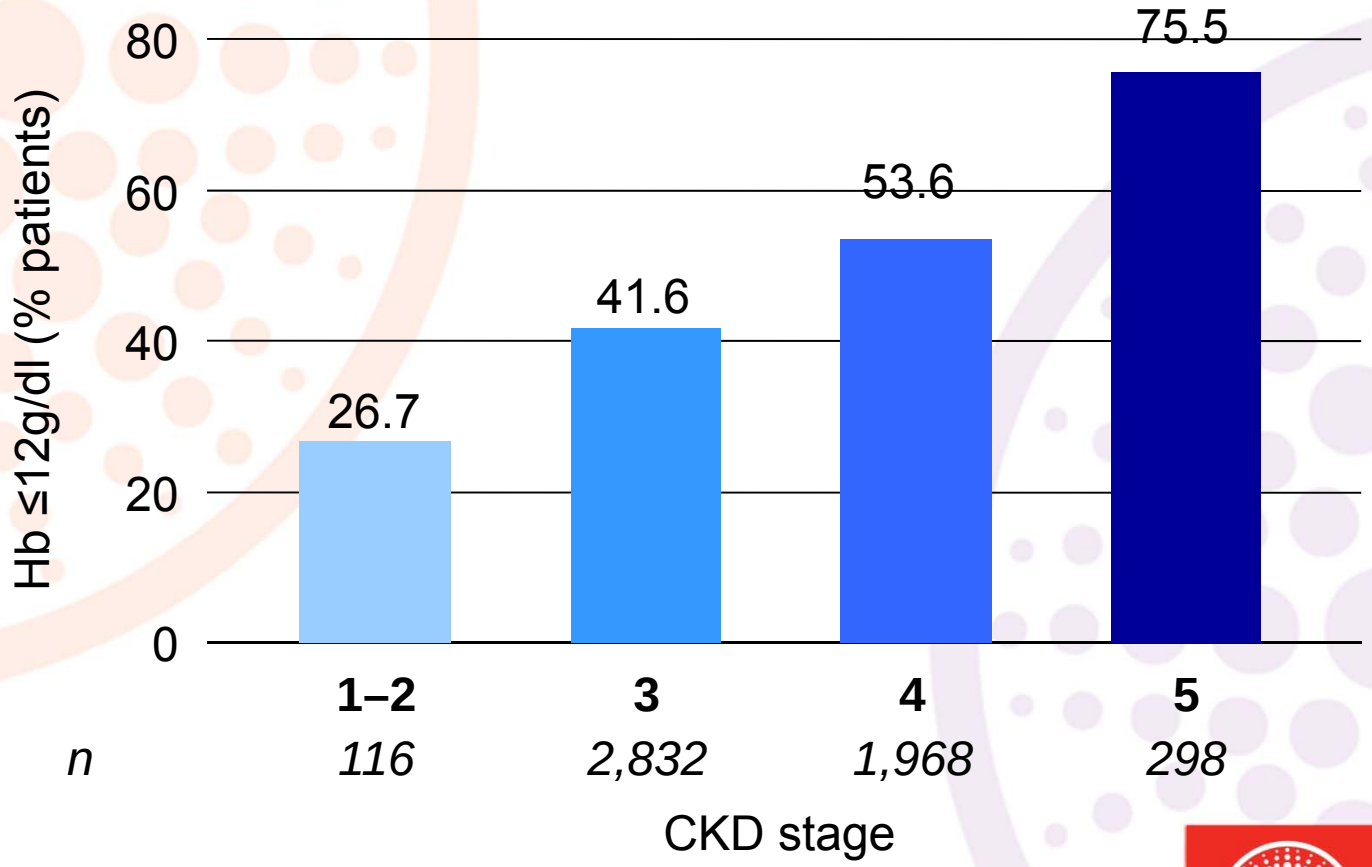
ferric carboxymaltose

Anemia is common in CKD frequency increases with severity of CKD



McClellan W et al. Curr Med Res Opin 2004; 20: 1501-1510

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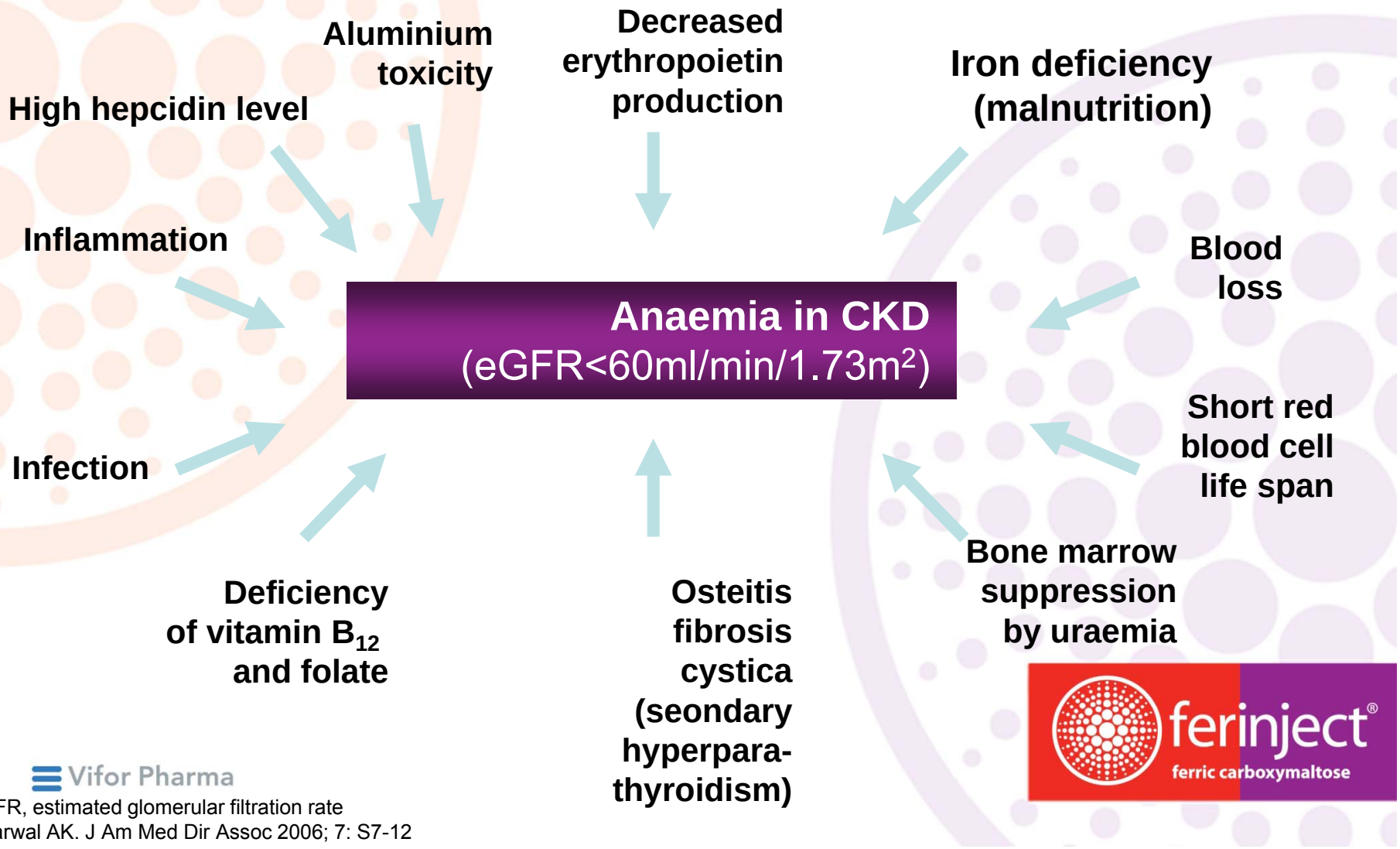
Factors contributing to anaemia in CKD



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eGFR, estimated glomerular filtration rate

Agarwal AK. J Am Med Dir Assoc 2006; 7: S7-12

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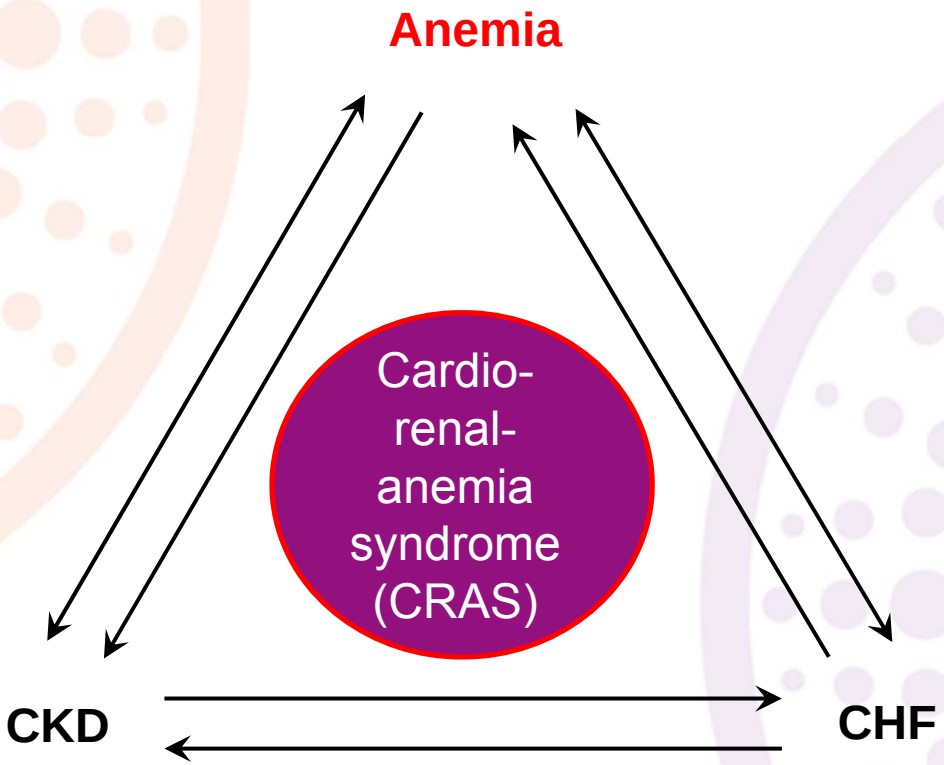
CKD, CHF and anemia exacerbate each other



Adapted from Besarab A et al. Oncologist 2009; 14(Suppl 1): 22-23

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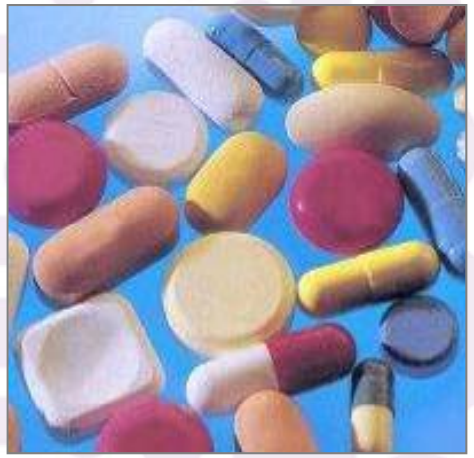
Oral iron supplementation

- Easy to administer
- Low cost
- Poor absorption from the gastrointestinal tract
- Gastrointestinal side effects
  - CKD stage 3-4 ($FeSO_4$ t.i.d.):

    constipation 35%, nausea 10%, vomiting 8%, diarrhea 6%[1]
- Variable compliance
- Interaction with medications
- Interaction with food



Charytan C et al. Nephron Clin Pract 2005; 100: c55-c62

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European Best Practice Guidelines recommendations

"The majority of, if not all, CKD patients will benefit from iron supplementation"

"Administration of I.V. iron in the absence of ESA therapy may improve anaemia in some renal patients, in particular CKD patients not yet requiring dialysis"

"There is strong evidence from randomised, controlled trials that treatment with I.V. iron is more effective than oral iron in renal failure patients"

Locatelli F et al. Nephrol Dial Transplant 2004; 19(Suppl 2): ii1-ii47

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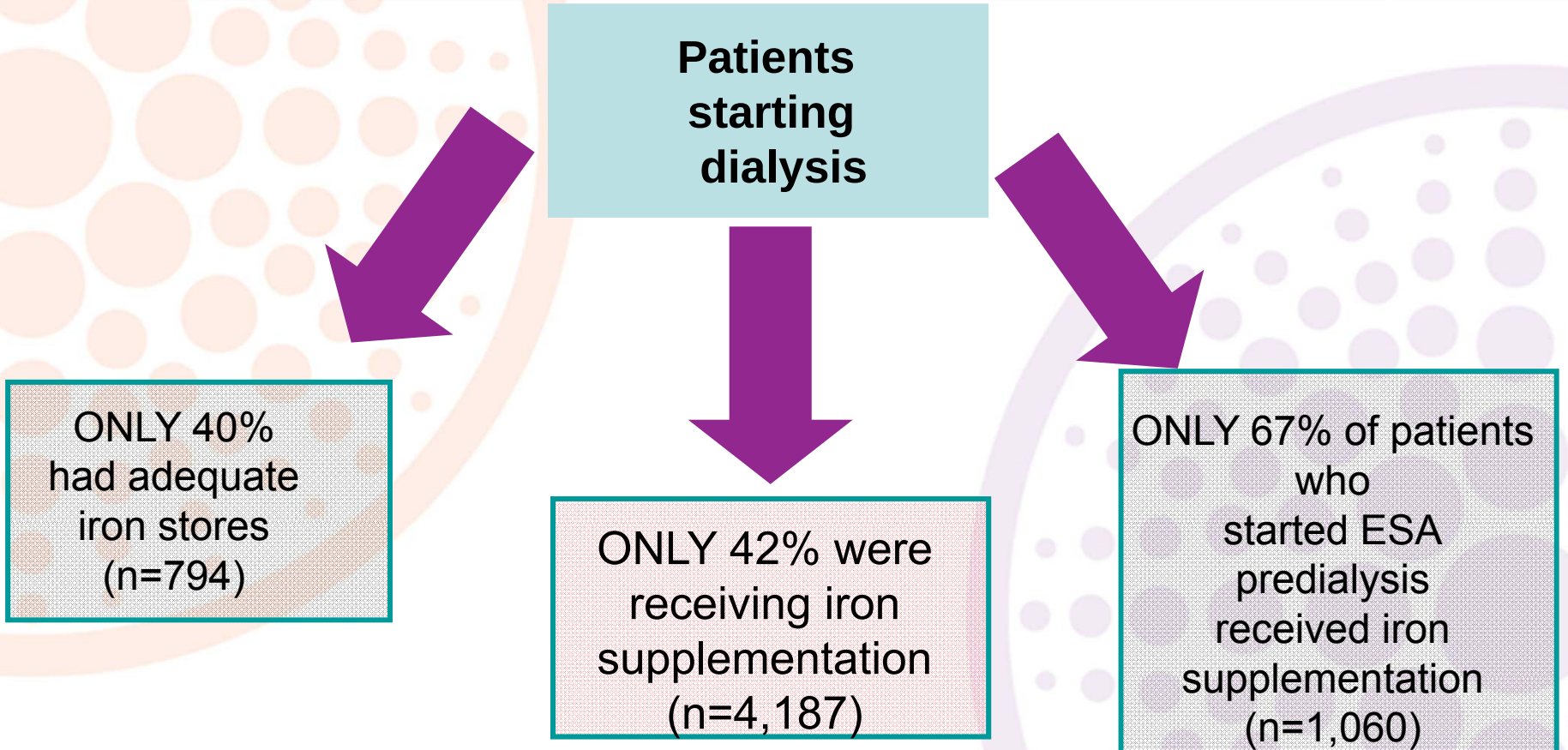
The role of iron therapy in managing IDA

- Iron supplementation is recommended for all CKD patients receiving ESA therapy and may delay/avoid the need for ESA therapy
- I.V. iron is more effective than oral iron supplements
  - Also avoids the disadvantages of oral iron (poor/variable absorption, gastrointestinal intolerance, compliance issues)
- Iron supplementation is under-used in ND-CKD patients

Iron deficiency is undertreated in ND-CKD



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Retrospective data from 1,997 patients starting dialysis 1999-2000 at 779 centres.
ESA, erythropoiesis stimulating agent
Valderrábano F et al. Nephrol Dial Transplant 2003; 18: 89-100

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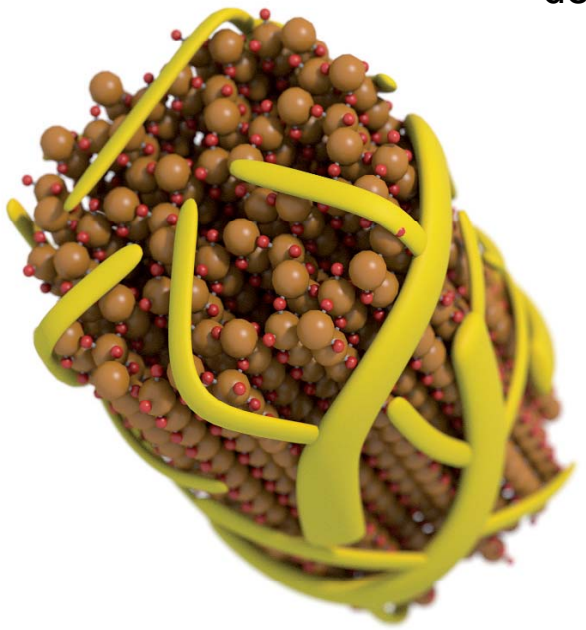
Ferinject® – Breakthrough next generation I.V. iron

Ferric carboxymaltose
Designed to overcome current I.V. iron limitations
Low immunogenic potential and iron-induced toxicity



❖Unique carbohydrate shell
- ✓ Highly stable, type I iron complex
- ✓ Dextran-free
- ✓ pH 5–7, physiological osmolarity

❖Rapid and selective delivery from plasma to:
- ✓ RES* of the liver
- ✓ Bone marrow

❖ Single dose up to 1000 mg
❖ No test dose required

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Low risk of immunogenicity and injection site reactions

- No dextran, low risk of immunogenicity with Ferinject
- Ferinject does not contain immunogenic triggers
- Ferinject does not cross-react with anti-dextran antibodies
- Ferinject has a near-neutral pH, limiting the likelihood of injection site reactions
- Ferinject osmolarity is comparable to that of blood

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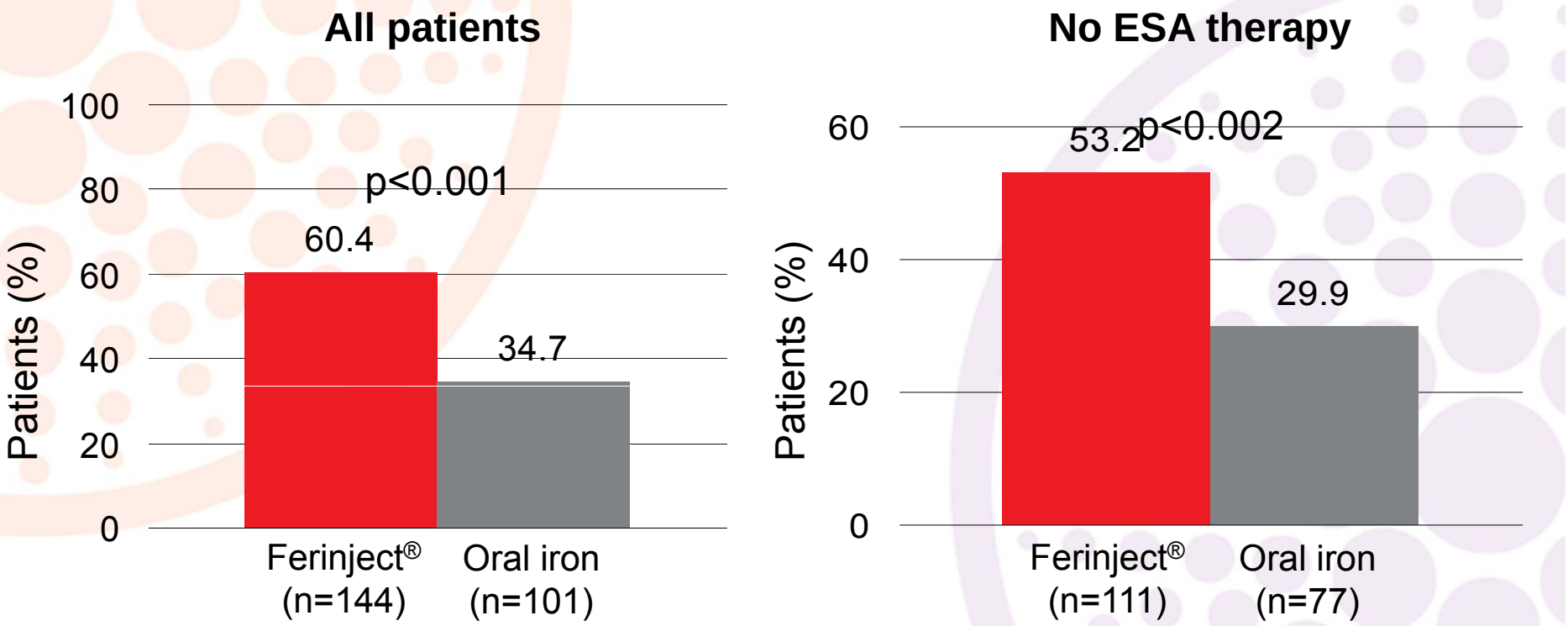
Efficacy is higher with Ferinject® than oral iron

Patients achieving Hb increase ≥1g/dl any time during the study (%)



Benjamin J et al. J Am Soc Nephrol 2009; 20: 666A (SA-PO2422)

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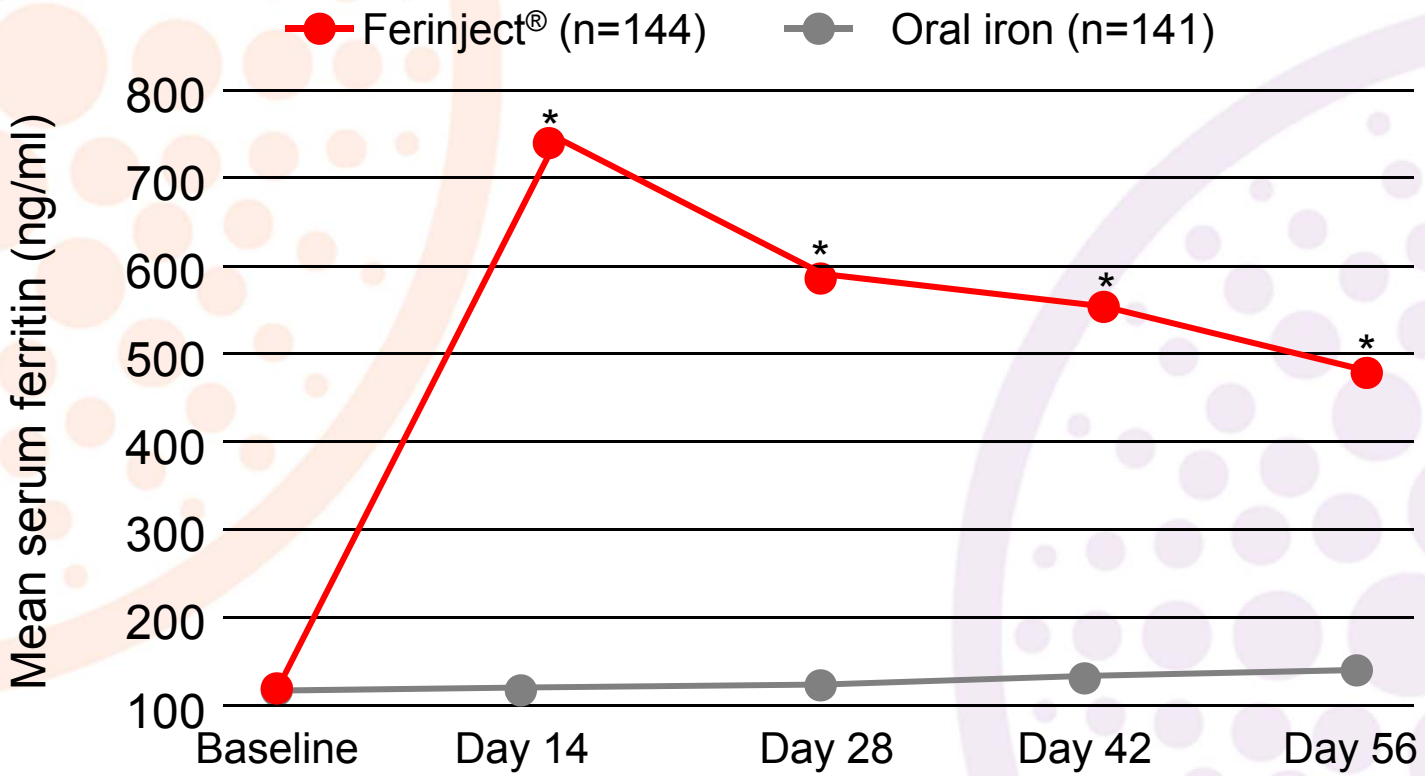
Higher serum ferritin levels achieved with Ferinject®



*p<0.001 vs. oral therapy and baseline

Qunibi W et al. ASN 2007. Poster SU-PO1030

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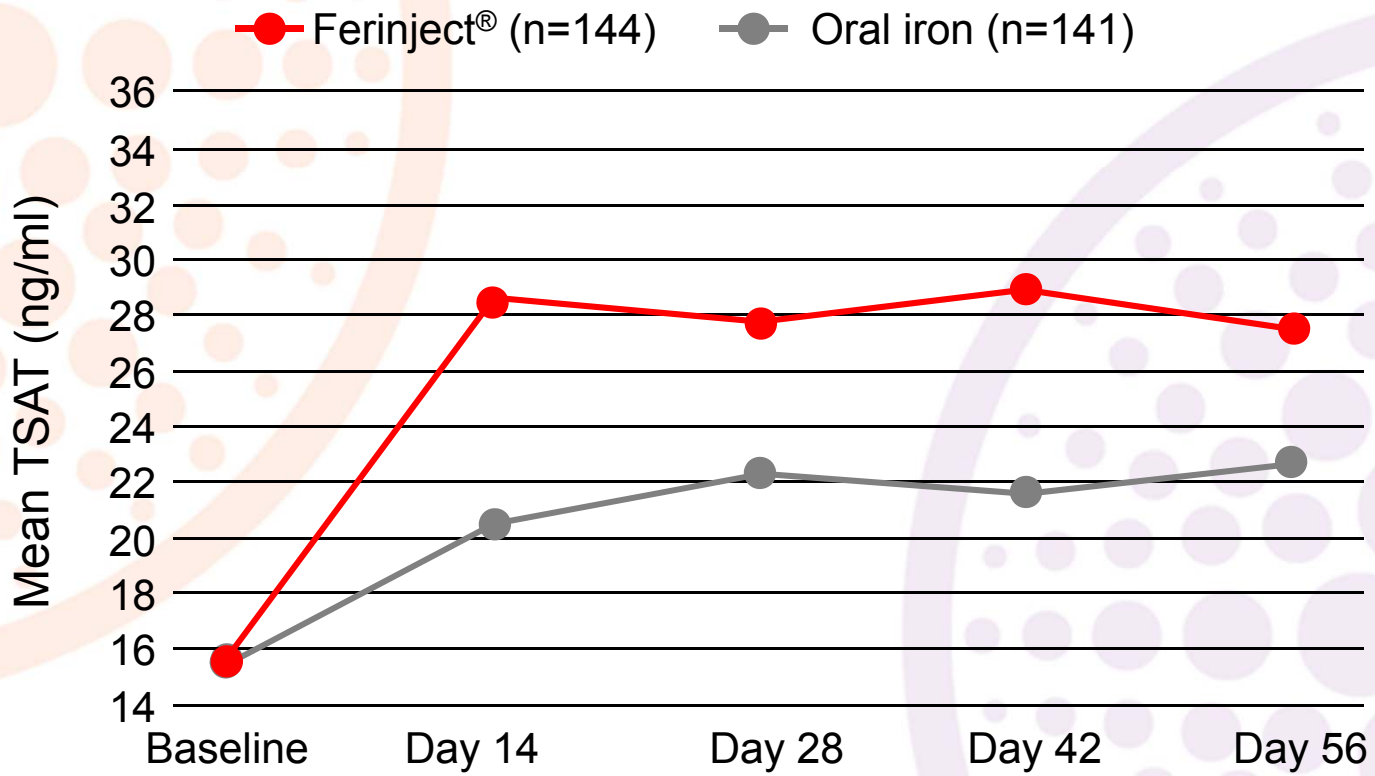
Higher TSAT levels achieved with Ferinject®



Qunibi W et al. ASN 2007. Poster SU-PO1030

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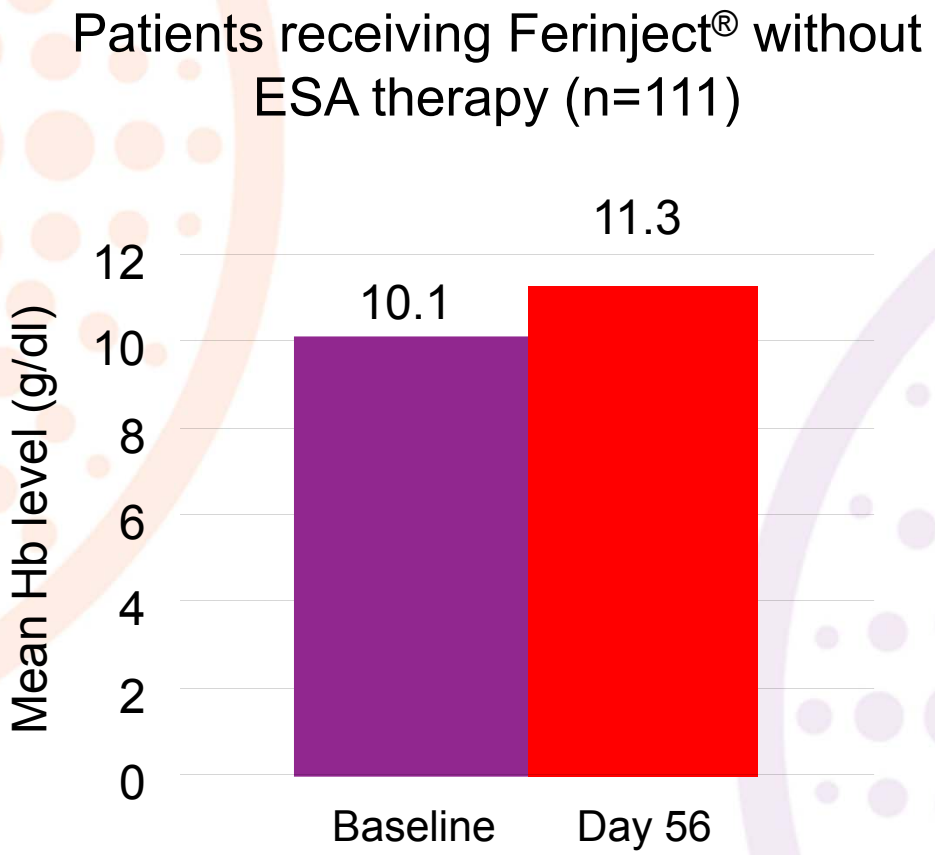
Ferinject® increases Hb level without ESA therapy



Benjamin J et al. J Am Soc Nephrol 2009; 20: 666A (SA-PO2422)

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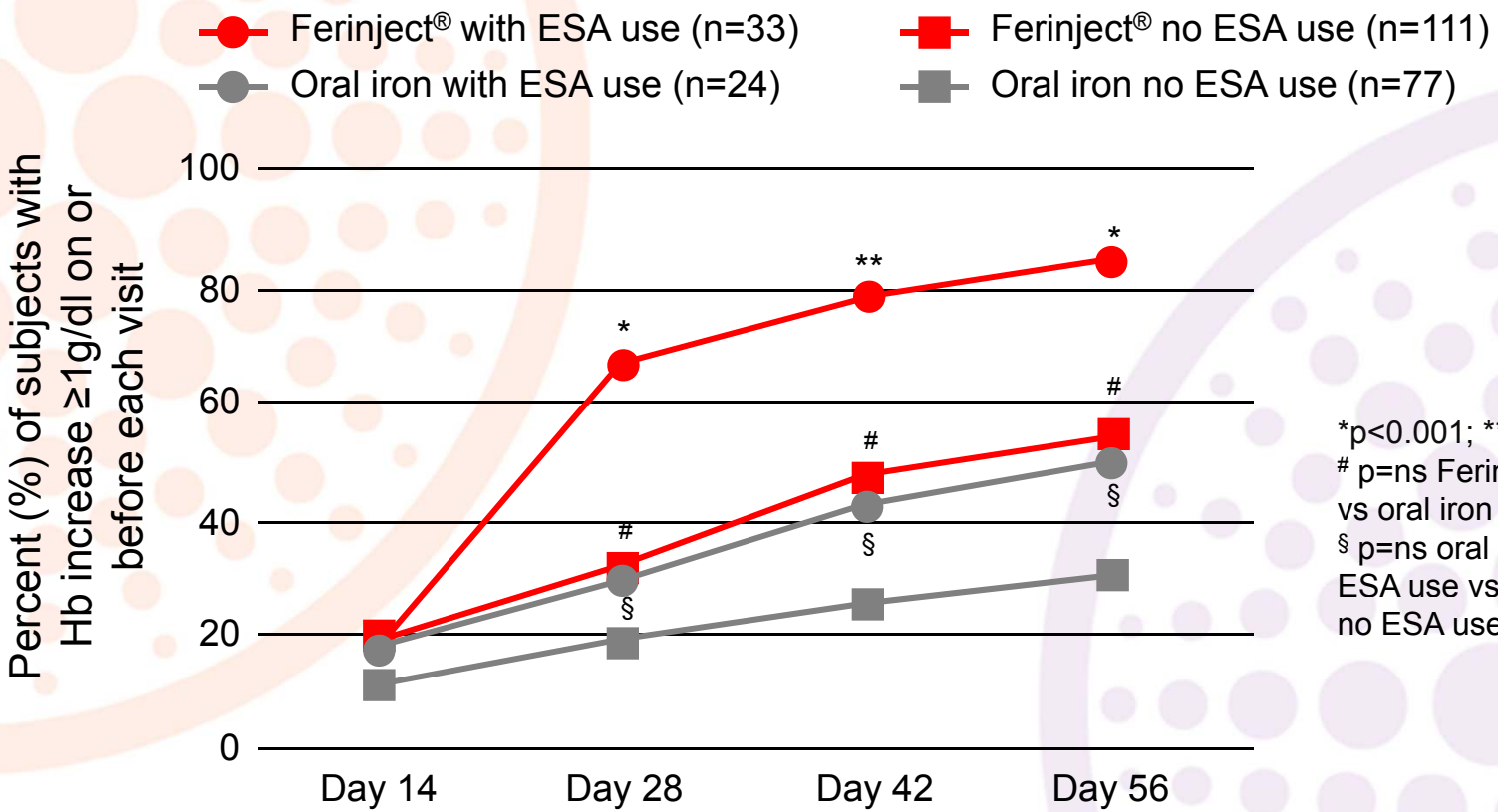
Comparable Hb increase with Ferinject® alone versus oral iron with ESA



*p<0.001; **p<0.01
p=ns Ferinject® no ESA vs oral iron with ESA use
§ p=ns oral iron with ESA use vs oral iron no ESA use

During the study in the FCM group in five patients the ESA dose was increased and in one patient initiated, in the oral iron group in two subject ESA dose was increased.

Benjamin J et al. J Am Soc Nephrol 2009; 20: 666A (SA-PO2422)

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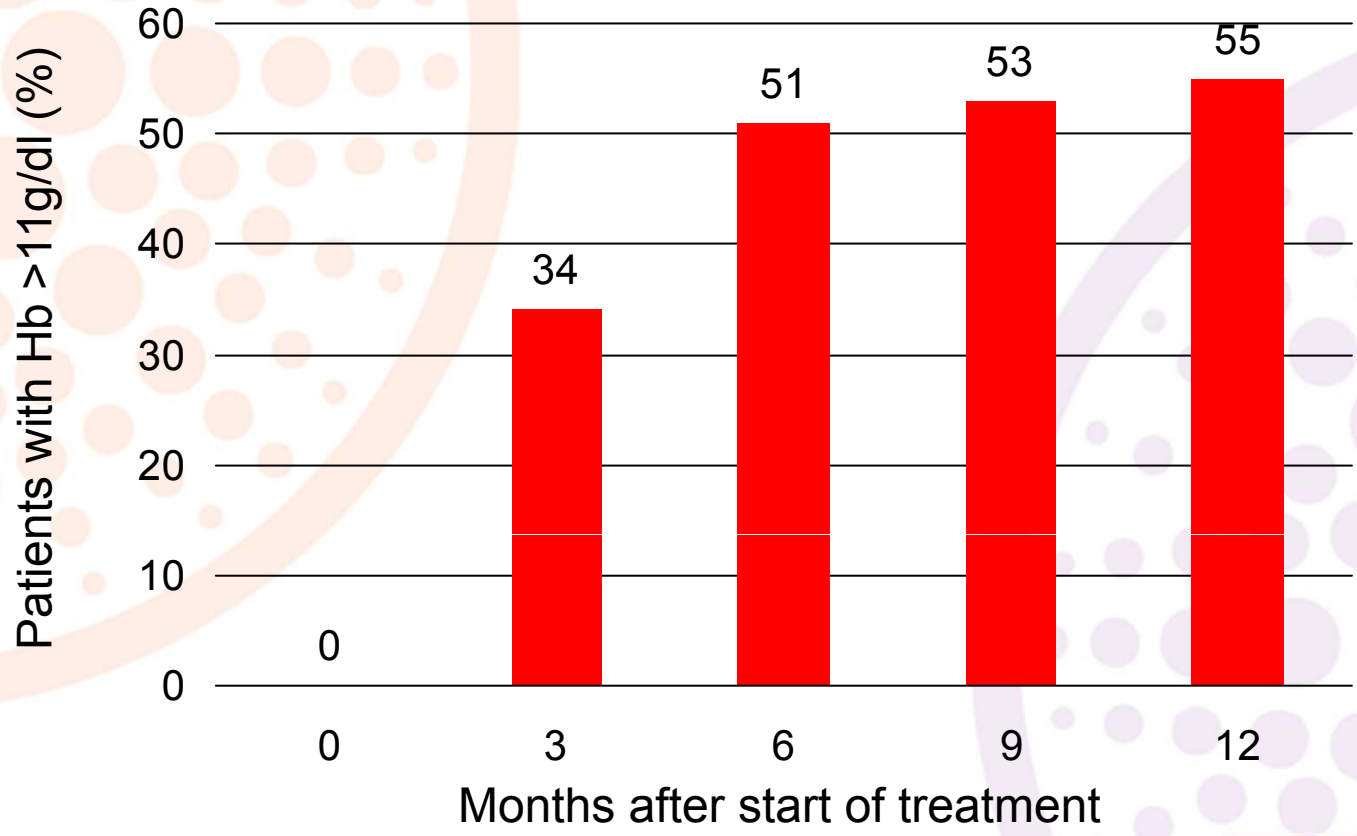
Hb target can be reached in many ND-CKD patients using I.V. iron without ESA



Mircescu G et al. Nephrol Dial Transplant 2006; 21: 120-124

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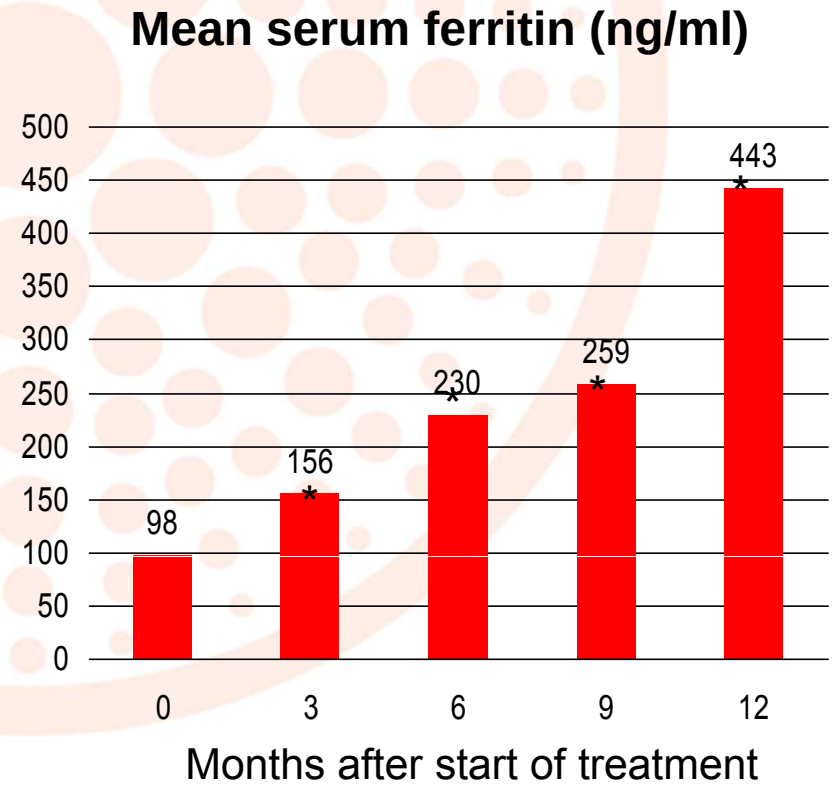
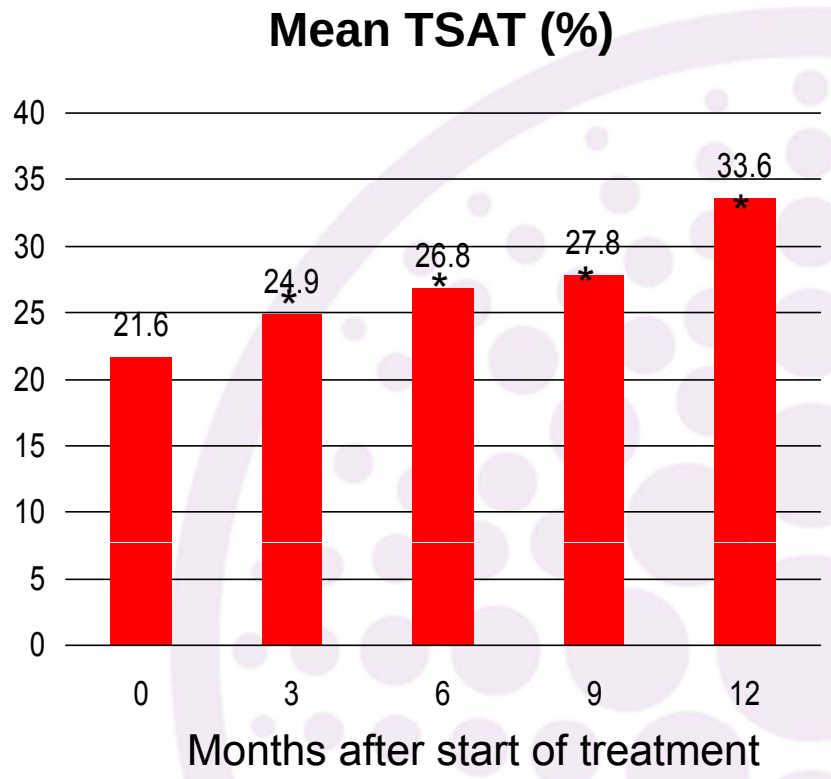
I.V. iron without ESA also significantly improves iron status





*p<0.05 versus month 0

Mircescu G et al. Nephrol Dial Transplant 2006; 21: 120-124

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I.V. iron may delay or even avoid the need for ESA therapy (1)

Mean increase in Hb with I.V. iron alone

	Benjamin et al, 2009[1]	Tagboto et al, 2009[2]	Tagboto et al, 2008[3]	Mircescu et al, 2006[4]	Spinowitz et al, 2008[5]
Study design	Prospective, open-label, randomized, multicenter	Retrospective, single-center	Retrospective, single-center	Prospective, single-arm, single-center	Prospective, open-label, randomized, multicenter
Time period	56 days	30 days	28 days	12 months	35 days
Therapy	Ferinject®	Ferinject®	Venofer®	Venofer®	Ferumoxytol
N	111	30	82	60	145
Mean increase in Hb (g/dl)	**1.16**	**0.73**	**0.53**	**1.6**	**0.62**

1. Benjamin J et al. J Am Soc Nephrol 2009; 20: 666A (SA-PO2422)
2. Tagboto S et al. J Ren Care 2009; 35: 8-23
3. Tagboto S et al. J Ren Care 2008; 34: 112-115
4. Mircescu G et al. Nephrol Dial Transplant 2006; 21: 120-124
5. Spinowitz BS et al J Am Soc Nephrol 2008; 19: 1599-1605

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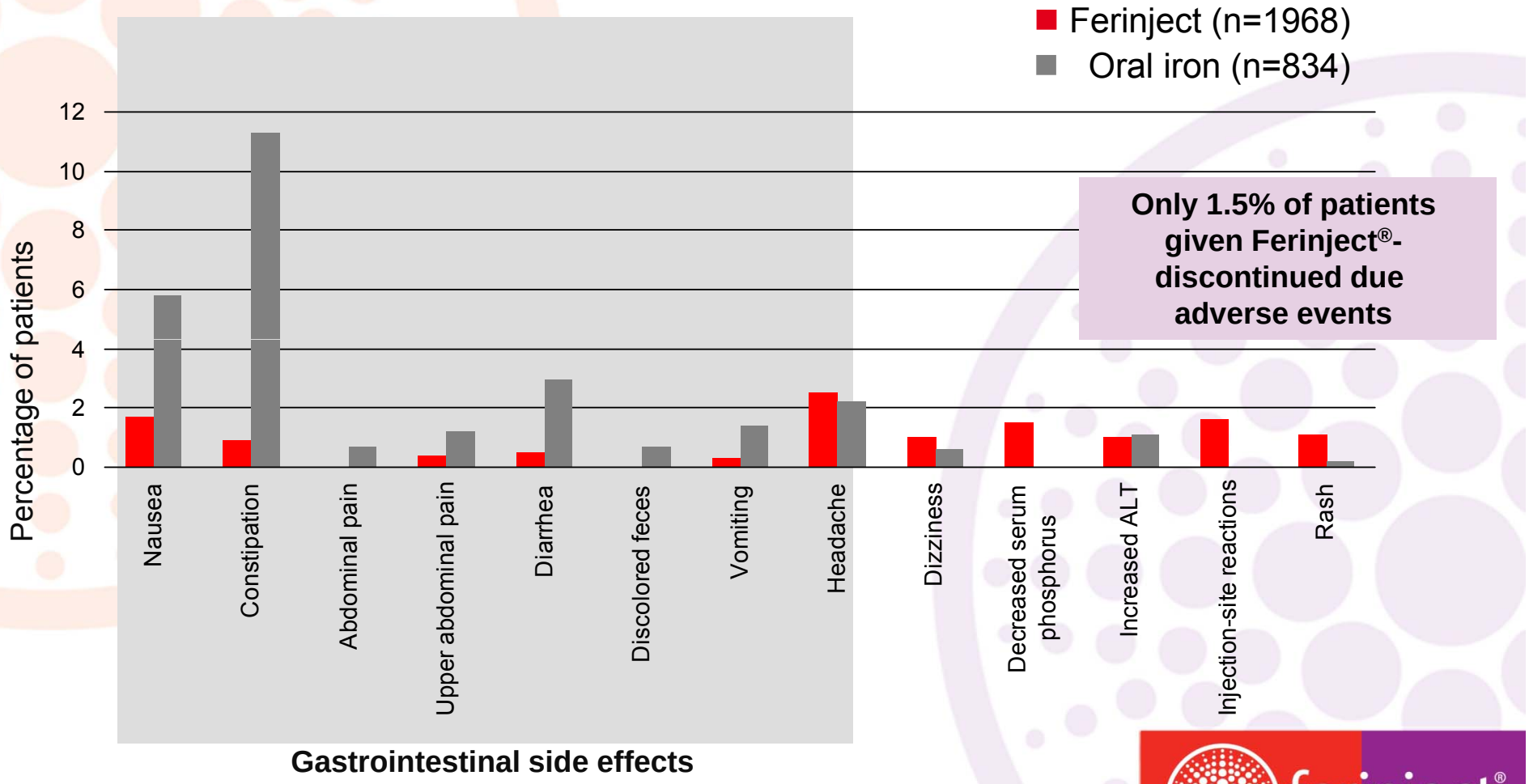
Fewer adverse events with Ferinject® than oral iron



Only 1.5% of patients given Ferinject®-discontinued due adverse events

Lyseng-Williamson KA et al. Drugs 2009; 69: 739-756

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Fewer adverse events with Ferinject® than oral iron in ND-CKD patients

	Ferinject® (n=147)	Oral iron (n=103)	P value
Drug-related adverse events	2.7%	26.2%	<0.0001
Serious adverse events	8.8%	9.7%	–
Drug-related serious adverse events	0%	0%	–

Benjamin J et al. J Am Soc Nephrol 2009; 20: 666A (SA-PO2422)

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Ferinject® key messages

- Anemia and iron deficiency are twin burdens facing ND-CKD patients
- Treatment patterns do not reflect guidelines
- Ferinject® fulfils unmet medical needs
- Ferinject® is significantly more efficient than oral iron
- Ferinject® is well tolerated compared to oral iron
- Ferinject® offers minimum intervention and maximum flexibility

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Ferinject® – Minimal intervention, maximum impact

High dose drip infusions

single dose up to 1000 mg iron
in 15 minutes only
no test dose required

500 mg (10 ml)
concentration 50 mg iron/ml

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Thank you

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