Author/Title Journal/Year	Type of Study	Outcomes Studied	Patient Characteristics	Results	HCFA Comments
Al-Momen AK, Huraib S, Mitwalli A, et al / Intravenous iron saccharate in hemodialysis patients receiving r-HuEPO / Saudi Journal of Kidney Diseases and Transplantation / 1994	Cohort study	Effects of erythropoietin therapy (EPO) and intravenous (IV) iron (Fe) saccharate were assessed using hemoglobin (Hb), hematocrit (Hct), serum iron, serum ferritin (SF), and total iron binding capacity (TIBC) as primary endpoints.	109 hemodialysis (HD) patients were enrolled into the study. All were treated with EPO therapy for a minimum of 8 weeks. Patients who were iron deficient were given 100 units/kg of EPO. Patients who were not iron deficient were given 50 units/kg of EPO. Patients that were excluded from the study had active bleeding, hemoysis, inflammation, infection, or malignancy. Patients were divided into 2 treatment groups. Group 1 (n=58) received high dose IV Fe (500mg). Group 2 received low dose IV Fe (100mg).	Group 1 had 42 iron deficient patients and 16 non-iron deficient patients. Group 2 had 22 iron deficient patients and 29 non-iron deficient patients. All patients from both groups showed statistically significant increase in Hct, Hb, TIBC, SF levels at the 4th week of IV Fe administration. EPO doses for the iron deficient patients were also lowered to 50 units/kg. Group 1 experienced adverse effects in 9 patients. None were reported in Group 2.	Study prov data on th dose-relat effectivene IV Fe sacc There was description how sampl groups we divided; la randomiza may introd selection b Furthermo analysis m mention of distinction made betw iron deficie non-iron deficient. Authors st patients w functional deficiency excluded, they did n elaborate No compar were made oral iron.
Bailie G, Johnson C, Mason N / Parenteral iron use in the management of anemia in end-stage renal disease patients / American Journal of Kidney Diseases / 2000	Overview	Not a clinical trial.	Not a clinical trial.	Not a clinical trial.	Article pro comparativ review of t available literature c safety, tox and clinica effectivene three IV Fe agents: iro dextran, ir

					sucrose, a gluconate.
Domrongkitchaiporn, S Jirakranont B, Aramasnkul K, Ungkanont A, Bunyaratvej A / Indices of iron status in continuous ambulatory peritoneal dialysis patients / American Journal of Kidney Diseases / 1999	Cohort study	Complete blood count (CBC), reticulocye HgB content, SF, TSAT, C-reactive protein, and intact parathyroid hormone levels were measured. Patients with a sustained increase in Hb content of greater than 1 gm/dL within 3 months after Fe infusion were defined as being Fe deficient. Those who did not were defined as nonresponders.	23 CAPD patients were eligible for the study. 2 patients were excluded (death from pneumonia & discontinuation of EPO). No change in EPO dose was allowed. Patients were given IV Fe sucrose. Inclusion criteria: stable CAPD for at least 3 months, receiving constant doses of EPO and oral Fe for at least 3 months, Hgb < 10 gm/dl, no hematological disorders other than anemia, no iv fe therapy for at least 1 month before study, no liver dysfunction of systemic illness that affects response to epo. Exclusion criteria: significant bleeding or blood transfusions; hospitalization, surgery, of infection requiring antibiotics; receiving other	21 patients completed the study. 15 patients (71.4%) responded to treatment and were considered Fe deficient. No adverse reactions developed during treatment. 9 of 13 (69%) patients with presence of bone marrow-stainable iron still responded to therapy. The authors calculate sensitivity/specificity values for the iron status indicators based on their ability to predict response to treatment	Study is m designed t assess the sensitivity specificity indices use measure ir status. It i difficult to extrapolat conclusion regarding effectivene IV iron suc

			forms of Fe supplementation; change in EPO dose; adverse reaction to IV Fe therapy; or poor compliance.		
Faich G, Strobos J / Sodium ferric gluconate complex in sucrose: safer intravenous iron therapy than iron dextrans / American Journal of Kidney Diseases / 1999	Retrospective analysis of market data	Safety of IV Fe gluconate complex (Ferrlecit) was compared to IV Fe dextran using adverse reaction rates and case-fatality rates .	Adverse event reports from the World Health Organization (WHO) were used to assess adverse reactions. Manufacturers of the iron products were contacted to estimate the number of units sold annually.	-- 3.3 allergy episodes per million doses sold for sodium ferric gluconate. -- 8.7 allergy episodes per millions doses sold for iron dextran. IV Fe gluconate had a substantially lower case fatality rate compared to Fe dextran (0 vs. 15.8%).	While the absolute n of episode reported suggests a distinction portion of number of administer difference miniscule (0.000003 0.000087 study does address cli effectivene one produ compared the other.
Frankenfield D, Johnson C, Wish J, Rocco M, Madore F, Owen W / Anemia management of adult hemodialysis patients in the US: results from the 1997 ESRD Core Indicators Project / Kidney International / 2000	Epidemiological study	Hct, TSAT, SF, weekly EPO dose, serum albumin and iron prescription practices were assessed.	Analysis was conducted on the medical records of a random sampling of Medicare-eligible ESRD patients who were receiving in-center HD on 12/31/96. Patients who were not on EPO were excluded from analysis. Of a sample of 7292 patients, 4991 were included in the final analysis.	The mean Hct for the entire sample was 32.6% +/- 3.5%. 72% of patients had a Hct > 30%, while 42% had Hct between 33 - 36%. Mean SF level was 386 ng/ml +/- 422 ng/ml. 79% had levels greater than or equal to 100 ng/ml. 77% of patients were prescribed iron (in some form) at least once in the 3 month study. Only 54% patient were prescribed IV Fe.	Study high current sta hematolog indicators anemia wit the Medica ESRD popu The author point out t need for b iron prescr practices, especially Fe therapy
Hussain R, Chishti S, Naqvi S / Experience	Cohort study	Hb, Hct, TSAT, EPO dosage,	20 HD patients were enrolled	Group 1 2 Hb init. 7.8	Study prov some evid

of iron saccharate supplementation in haemodialysis patients treated with erythropoietin / Nephrology / 1998		and SF levels were monitored and compared as iron-replete patients underwent either oral iron therapy or IV Fe saccharate therapy for 3 months.	into the study. Patients had Hb < 8.5 g/dl, normal folate and b12 level, sf between 200 and 800 ng/ml, and tsat > 30%. Patients were split into 2 groups: Group 1 (n=10) were on IV Fe saccharate (100mg), Group 2 (n=10) were given oral Fe (60mg) 3 times a day. EPO therapy was also commenced on both groups. Dosage was adjusted according to Hb.	8.0 end 11.6 10.5 p-val <0.001 <0.001 SF init. 386 446 end 671 367 p-val <0.05 =0.50 Target Hb (11-12 G/dl) was achieved in all Group 1 patients except one. Only 5 patients achieved target Hb levels in Group 2. EPO dose was increase in 1 patients from Group 1 and 6 patients in Group 2.	that iron-r patients tr with IV Fe saccharate a better response t therapy compared those on o iron therap sample siz in each gr quite smal addition, p were not randomize between th treatment groups. However, authors' re are consist with findin from other clinical stu
Jones C, Richardson D, Ayers S, Newstead C, Will E, Davison A / Percentage hypochromic red cells and the response to intravenous iron therapy in anaemic haemodialysis patients / Nephrology Dialysis Transplantation / 1998	Cohort study	Hgb, SF, and % hypochromic red cells (%HRC) were measured. SF and Hgb at baseline and the 8th weeks were compared.	98 patients on chronic HD with persistent anemia (Hb < 10 g/dl) and sf levels < 100 micrograms/l were initially studied. prior to the study these patients were on a maximum tolerate dose of oral fe. patients were given 200 mg of iv fe sucrose weekly. study takes place over a 8-week period. epo doses were not adjusted during study. 15 patients were	Data for 82 patients were available for analysis. At baseline, there were no differences in EPO dose, Hgb, or SF according to %HRC. SF increased significantly in all subgroups. Overall, 37 patients had to discontinue therapy after 4 weeks because SF exceeded 250 micrograms/L. Increase in Hgb was also significant in all groups, but the increase was greater with increasing %HRC.	The study designed t assess the of %HRC i diagnosing patient wit deficiency. division of patients according HRC levels makes it d to extrapo any conclu regarding comparabl effectivene IV Fe thera

			excluded from analysis because of blood transfusions or organ transplantations; 1 patient was excluded because of possible anaphylaxis to iv iron therapy. The response to Fe therapy was assessed according to 3 groups of %HRC (0-3%, 4-9%, or greater than 10%).		
Macdougall I, Chandler G, Elston O, Harchowal J / Beneficial effects of adopting an aggressive intravenous iron policy in a hemodialysis unit / American Journal of Kidney Diseases / 1999	Cohort study	EPO dose, Hgb, SF levels were examined.	Study examined all 116 HD patients in dialysis unit from November 1997 to November 1998. Regular weekly IV Fe (100 mg of Fe sucrose per dialysis session) to all HD patients whose SF levels were between 150 and 1000 micrograms/L. IV iron was only withheld if SF was < 1000 micrograms/l at any stage. Patients with SF < 150 micrograms/l were given a more aggressive	Mean (standard deviation) 11/97 11/98 EPO 13277 (6337) 8976 (6158) Hgb 9.6 (2.0) 10.7 (1.9) SF 214 (246) 564 (350) EPO - units/week Hgb - g/dL SF - micrograms/L 4564 injections were given over a year. No adverse reaction was recorded. There were no dramatic increases in infections rates pre and post treatment.	The study largely an observatio uncontrolle study that monitored patients undergoing dialysis wh administer sucrose. S provides s evidence o effectivene IV Fe sucr pre-dialysi patients. T there is no compariso other mod iron treatm (oral iron o iron), the r are fairly consistent those foun other stud

			regimen of iv iron until levels increased above threshold.		
National Kidney Foundation Study Group / National Kidney Foundation-Dialysis Outcomes Quality Initiative clinical practice guidelines for the treatment of anemia of chronic renal failure: iron support / American Journal of Kidney Diseases / 1997	Overview	Not a clinical trial.	Not a clinical trial.	Not a clinical trial.	Article pro backgroun material a guidelines need and u iron-suppo therapy fo patients.
Silva J, Andrade S, Ventura H, et al / Iron supplementation in haemodialysis--practical clinical guidelines / Nephrology Dialysis Transplantation / 1998	Cohort study	TSAT, hypochromic erythrocytes, Hb, SF, EPO dosage, and serum iron levels were monitored as patients were treated with IV Fe sucrose. An increase of 1 g/dl of Hb over initial value was considered a positive response to treatment and indicative of iron deficiency.	33 HD patients on EPO were selected from a dialysis unit who had met at least one of the following entry criteria: TSAT<20%, hypochromic erythrocytes > 10%, or SF < 400. 20 patients were on oral iron prior to the study. Patients were divided into 2 groups based on SF levels at baseline: Group 1 = SF< 100 (n=17), group 2 = 100<SF Patients were excluded if they had active inflammatory or infection disease,	Iron deficiency was diagnosed in 29 of the 33 patients. There was a progressive increase in mean Hb level (10.8 at baseline vs. 12.8 at 6 months [p<0.0001]). There was a progressive increase in mean SF level (137 at baseline vs. 456 at 6 months [p=0.0001]). A plateau effect was observed between the 4th and 6th month. EPO use decrease significantly by 28% (6871 at baseline vs. 4947 at 6 months [p<0.003]. There were no significant differences in Hb and hypochromic	Regardless levels, a significant portion of study popu was diagno as iron def This indica either that values alo insufficient diagnosing deficiency cutoff of 4 not adequa enough to indicate iro deficiency patients. Both group responded treatment. Although t was no compariso control gro the eviden presented demonstra the effecti

			hematological disease, psychosis, iron overload, need of blood transfusion, or change in renal replacement treatment	erythrocytes levels between the 2 groups. SF levels were significantly lower in Group 1 throughout the study. Serum iron and TSAT were similar in both groups at baseline but became significantly higher in Group 1 at the end. Group 1 required a lower dose of EPO throughout the study.	of IV Fe th in HD patie findings consistent other stud
Silverberg D, Blum M, Agbaria Z, et al / Intravenous iron for the treatment of predialysis anemia / Kidney International / 1999	Review	Not a clinical trial.	Not a clinical trial.	Not a clinical trial.	This article provides a review of t available literature c Fe use in predialysis anemia. Th authors als review the findings of of their ow studies. However, t is no detai description protocols c methodolo used to an the results making a thorough r and critiqu the clinical informatio difficult.
Silverberg D, Blum M, Peer G, Kaplan E, Iaina A / Intravenous ferric saccharate as an iron supplement in	Cohort study	Hct, EPO dosage, SF and iron saturation were monitored for 12 months as	73 patients on chronic dialysis (64 on HD, 9 on CAPD) were enrolled into the study. Patients	EPO Hct SF Grp 1 int. 98.8 28.7 99.0 0-6 98.8 33.7* 402.7*	The study provides g evidence c effect of IV therapy on EPO dose

iron supplement in dialysis patients / Nephron / 1996		12 months as patients underwent IV Fe saccharate therapy.	study. Patients had no signs of infection or gastrointestinal bleeding. Oral iron was not used either before or during the study. All patients were receiving phosphate binders. Patients were divided into five groups. HD patients: Group 1: IV Fe added in patients already taking EPO. Group 2: IV Fe and EPO started simultaneously. Group 3: IV Fe without EPO. CAPD patients: Group 4: Taking IV Fe and EPO Group 5: Taking IV Fe without EPO	6-12 38.4* 33.6* 383.3* Grp 2 int. 0 28.1 83.7 0-6 95.6 34.1* 369.9* 6-12 23.2* 33.9* 348.8* Grp 3 int. 0 30.5 49.0 0-6 0 37.5* 293.8* 6-12 0 37.9* 287.8* Grp 4 int. 61.4 28.4 102.8 0-6 61.4 33.3* 470.5* Grp 5 int. 0 27.7 144.6 0-6 0 35.6* 459.9* * = p < 0.05 vs. int.	EPO dose, SF levels. Furthermo data highli the effecti of IV Fe ev patients w not underg EPO treatn However, t sample siz each of the groups we quite smal Patients w also not randomize their respe groups.
Silverberg D, Iaina A, Peer G, et al / Intravenous iron supplementation for the treatment of the anemia of moderate to severe chronic renal failure patients not receiving dialysis / American Journal of Kidney Diseases / 1996	Case series	Serum creatine, creatine clearance, Hct, Hb, SF, iron, and TIBC levels were monitored as patients underwent IV Fe sucrose therapy.	333 patients with moderate to severe chronic renal failure were enrolled into the study. These patients were not receiving dialysis. 32 patients in the sample were hypertensive and undergoing treatment to control their blood pressure. All had Hb < 11.0 g/dl, been followed for at	By the end of the study (6 months) mean Hct and Hb levels increased by 19.% +/- 3.8% (p=0.035) and 0.6 +/- 1.2 g/dl (p=0.008) respectively. SF and iron saturation levels increased steadily as well (statistically significant). 22 patients (66.7%) experienced increases in Hb and Hct and were considered	Study prov some evid on the effectivene IV Fe sucr pre-dialysi patients. T there is no compariso other mod iron treatn (oral iron c iron), the r are fairly consistent those foun other stud should be however, t

			least 6 months prior to the study, and had been receiving oral iron supplements. no patient had previously been on epo. patients were followed on iv fe sucrose for 5 months.	responders. 11 patients had decreases in Hb and Hct and were considered non-responders. One patient was not included in the study because of an adverse reaction to the initial test dose.	nearly 1/3 study popu did not res to IV Fe treatment were no significant differences existed be responders nonrespon There are clear criter suggested will identif which pati will respon IV Fe thera
Silverberg D, Wexler D, Blum M, et al / The use of subcutaneous erythropoietin and intravenous iron for the treatment of the anemia of severe, resistant congestive heart failure improves cardiac and renal function and functional cardiac class, and markedly reduces hospitalizations / Journal of the American College of Cardiology / 2000	Retrospective cohort study	Hgb, LVEF, hospitalization rate pre- and post-treatment.	Medical records from 142 CHF patients being treated in a special outpatient CHF clinic were reviewed to determine the prevalence and severity of anemia and renal failure. Patients were referred to clinic by general practice or hospital wards. 26 of these patients had persistent, severe CHF (NYHA class > III) despite at least 6 months of treatment. These patients had Hgb < 12 and were resistant to maximally tolerated chf therapy. these patients	Study lasted for a mean of 7.2 months. The prevalence of anemia in the group of 142 patients increased with the severity of CHF. 79.1% of patients with NYHA class IV CHF had anemia (Hgb < 12). In the intervention group (n=26), mean Hgb and LVEF increased significantly. Mean number of hospitalizations decreased by 91.9% compared to rates prior to the intervention. NYHA class status also decreased.	The study uncontrolle observatio study that assesses t effectivene anemia manageme (using EPO IV Fe sucr patients w CHF. Given simultaneo introductio EPO and IV sucrose therapies i these patie is difficult assess the and effecti of IV Fe su alone. The does not a the effecti of IV Fe th in patients ESRD.

			participated in an intervention study. all were given a combination of epo and iv fe sucrose. dosages were adjusted to achieve and maintain a target hgb of 12. doses of other medications were kept constant.		
Sunder-Plassmann G, Horl W / Comparative look at intravenous iron agents: pharmacology, efficacy, and safety of iron dextran, iron saccharate, and ferric gluconate / Seminars In Dialysis / 1999	Overview	Not a clinical trial.	Not a clinical trial.	Not a clinical trial.	Article pro comparativ review of t available literature c safety, tox pharmacol and clinica effectivene three IV Fe agents: iro dextran, ir sucrose, a gluconate.
Tarng DC, Huang TP, Chen TW / Mathematical approach for estimating iron needs in hemodialysis patients on erythropoietin therapy / American Journal of Nephrology / 1997	Cohort study	Hb, Hct, SF and other iron metabolism parameters were measured regularly for 6 months. The main purpose of the study was to predict iron needs from Hb and SF levels and establish a formula that determines iron needs in patients with functional iron deficiency.	40 HD patients were enrolled into the study. Patients has an initial Hct > 25%. All patients has basal SF levels > 100. Patients were divided into 2 groups according to TSAT levels. Group 1 (n=20) had TSAT > or = 25% (not having functional iron deficiency), Group 2 (n=20) had TSAT < 25% (having functional iron	EPO dose increased significantly in both groups as compared to initial dose. At the end of the study, patients had a mean dose of 92 unit/kg/wk (Group 1) and 90 unit/kg/wk (Group 2). At 6 months, mean Hb were significantly elevated in both groups as compared to baseline. Mean SF significantly declined in Group 1 and significantly increased in Group 2. There was no	Study is m designed t develop a mathemat methodolo assessing needs in H patients or The divisio patients according TSAT level the administra IV Fe sucr only the functional deficient g makes it d to extrapo any conclu

			deficiency). epo was administered to both groups. group 2 patients also received iv fe sucrose.	significant change in TSAT in Group 1. Group 2 had a significant increase in TSAT. At the end of the study 18 patient in each group (90%) had TSAT > 25%.	regarding comparabl effectivene IV Fe thera is interesti note that t iron-replet group with > 25% (w did not rec iron supplemen still experi a significa decline in stores.
Van Wyck D, Al-Saloum M, Charytan C, Hafeez T, Levin N / Efficacy and safety of iron sucrose for iron deficiency in patients with dialysis-associated anemia: North American clinical trials / Journal of the American Society of Nephrology / 1999	Cohort study	Hgb, SF, and TSAT were all assessed for changes after administration of IV Fe sucrose.	24 dialysis patients were initially examined. These patients demonstrated stable EPO therapy, Hgb < 11 g/dl, tsat < 20%, and sf < 300 ng/ml. Patients were given IV Fe sucrose. EPO doses were not adjusted. Patients were assessed at baseline (n=24), 24 days (n=20), 36 days (n=19), and 57 days (n=15).	Day Hgb TSAT SF Base 10.1 17.0 100 24 11.2 28.3 404 36 11.6 29.6 304 57 11.8 24.4 206 Analysis indicates that increases in Hgb, SF, and TSAT were statistically significant. Study patients received a total of 170 doses iron. No adverse events were reported.	The abstra does not c sufficient evidence t thoroughly review and critique th clinical informatio study prot No explain given rega patient att
Van Wyck D, Cavallo G, Spinowitz B, et al / Safety and efficacy of iron sucrose in patients sensitive to iron dextran: North American clinical trial / American	Cohort study	Primary outcome measure was a increase in Hgb levels greater than 0.5 g/dL. Secondary	Study looked at 23 adult patients undergoing HD with EPO and anemia who had documented evidence of sensitivity to IV	22 patients completed the study (one patients withdrew from Group A when unstable angina developed unrelated to Fe therapy).	Although t study asse the safety Fe sucrose patients w documente dextran sensitivity,

Journal of Kidney Diseases / 2000		outcome measures include increases in TSAT, SF, and serum Fe-binding capacity. All patients were included in an intent-to-treat analysis.	Fe dextran and an Hgb level < 11.0 g/dl. all patients who met the above criteria were included. Patients were assigned to two treatment groups based on severity of their reactions to IV Fe dextran: Group A (n=16) had history of mild reactions, Group B (n=7) had history of severe reactions. Eligibility for Group B also required evidence of Fe deficiency (TSAT < 20% and sf < 300 ng/ml). all patients were given iv fe sucros e. Patients were excluded for the following reasons: inflammatory disease, causes of anemia other than ESRD or Fe deficiency, asthma, pregnancy, bacterial or viral infection, severe cardiac, hepatic, or psychiatric disorder, need for transfusion, surgery or transplantation during study	to Fe therapy). A 223 doses of Fe sucrose were administered during the study. There were no serious adverse reactions recorded, no episodes of anaphylaxis, no patient withdrawal, and no drug discontinuation caused by drug-related adverse events. 3 mild adverse events possibly related to the IV Fe sucrose were observed in 2 patients. All efficacy outcomes showed a significant degree of improvement after therapy. Increase in Hgb levels was first significant at day 15 after 6 doses of the drug. EPO doses were stable prior to study and declined slightly during the study.	gives no indication the advers reaction ra general sa data of Fe sucrose in general population also does n compare IV sucrose's s profiles wit of iron dex the genera population

			period, and evidence of Fe overload.		
Vychytil A, Haag-Weber M / Iron status and iron supplementation in peritoneal dialysis patients / Kidney International / 1999	Review	Not a clinical trial.	Not a clinical trial.	Not a clinical trial.	This article provides a review of t available literature o Fe use in peritoneal dialysis pa The author review the findings of of their ow studies. However, t is no detai description protocols o methodolo used to an the results making a thorough r and critiqu the clinical informatio difficult.