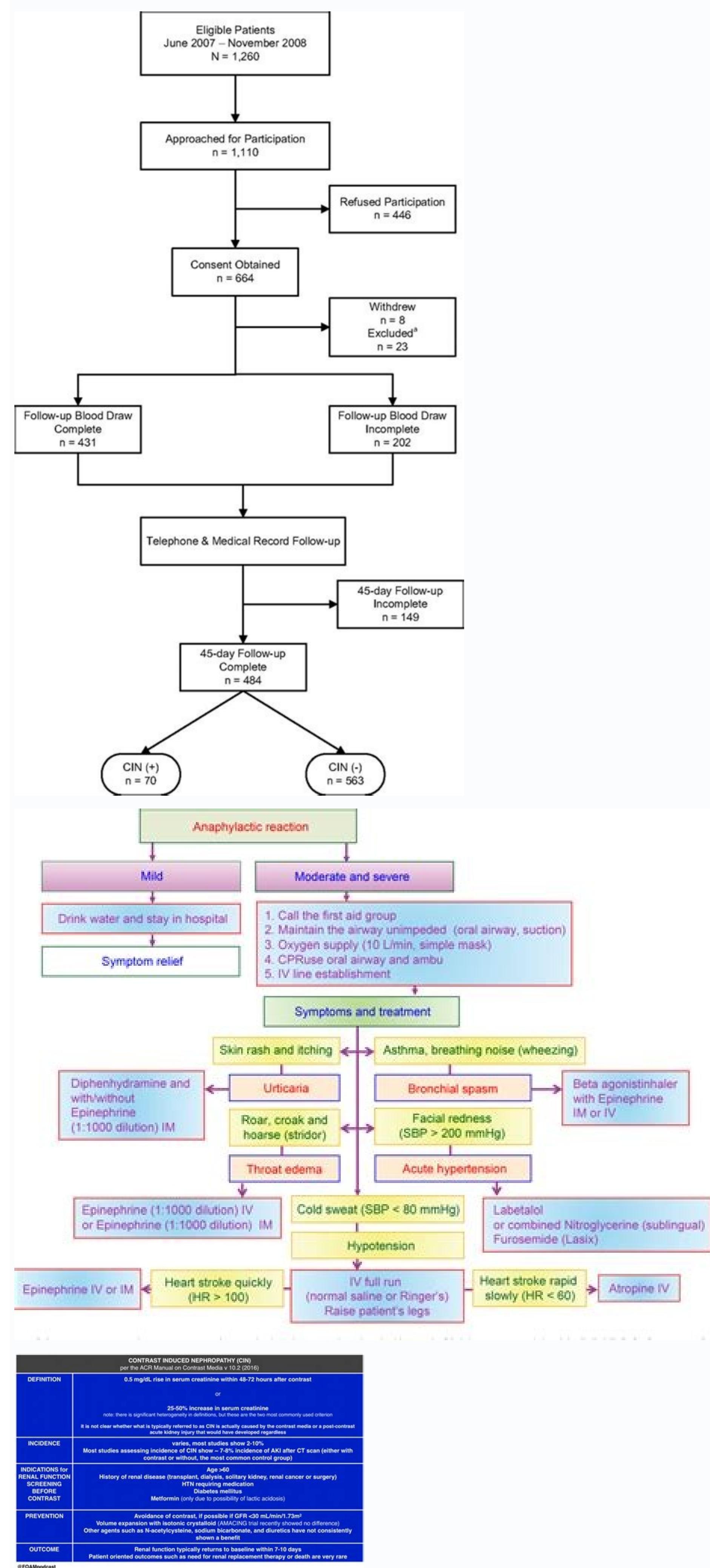


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CONTRAST INDUCED NEPHROPATHY (CIN) per the ACR Manual on Contrast Media v 10.2 (2016)	
DEFINITION	0.5 mg/dL rise in serum creatinine within 48-72 hours after contrast
INCIDENCE	25-50% increase in serum creatinine note: there is significant heterogeneity between studies, but an estimate of the most commonly used contrast It is not clear whether what is typically referred to as CIN is actually caused by the contrast media or a post-contrast acute kidney injury that would have developed regardless
INDICATIONS for RENAL FUNCTION TESTING BEFORE CONTRAST	Varies, most studies show 2-10% Most studies assessing incidence of CIN find the incidence of AKI after CT scan (either with contrast or without, the most common control group)
PREVENTION	Age >60 History of renal disease (transplant, dialysis, solitary kidney, renal cancer or surgery) HTN (hypertension) Diabetes mellitus Metformin (only due to possibility of lactic acidosis)
OUTCOME	Renal function typically returns to baseline within 7-10 days Patient oriented outcomes such as need for renal replacement therapy or death are very rare

The prevention of contrast induced nephropathy by sarpogrelate in patients with chronic kidney disease: a study protocol for a prospective randomized controlled clinical trial

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Abstract

Background: Contrast-induced nephropathy (CIN) is a serious clinical problem associated with increased morbidity and mortality, particularly in patients with chronic renal insufficiency. Although some agents including hydration with saline are being prescribed to prevent renal deterioration in these high risk patients, their efficacy is not clearly defined and debatable. Therefore additional prophylactic pretreatments are needed.

Methods/Design: The present study aims to investigate differences in occurrence of CIN after sarpogrelate premedication in patients with chronic kidney disease (CKD). 268 participants, aged 20-85 years with a clinical diagnosis of CKD will be recruited. They will be randomly allocated to one of two conditions: (i) routine treatment without sarpogrelate, and (ii) routine treatment with sarpogrelate (a fixed-flexible dose of 300 mg/day). The primary outcome is the occurrence of CIN during 4 weeks after receiving contrast agent.

Discussion: As of May 2010, there were no registered trials evaluating the therapeutic potentials of sarpogrelate in preventing for CN. If sarpogrelate decreases the worsening of renal function and occurrence of CN, it will provide a safe, easy and inexpensive treatment option.

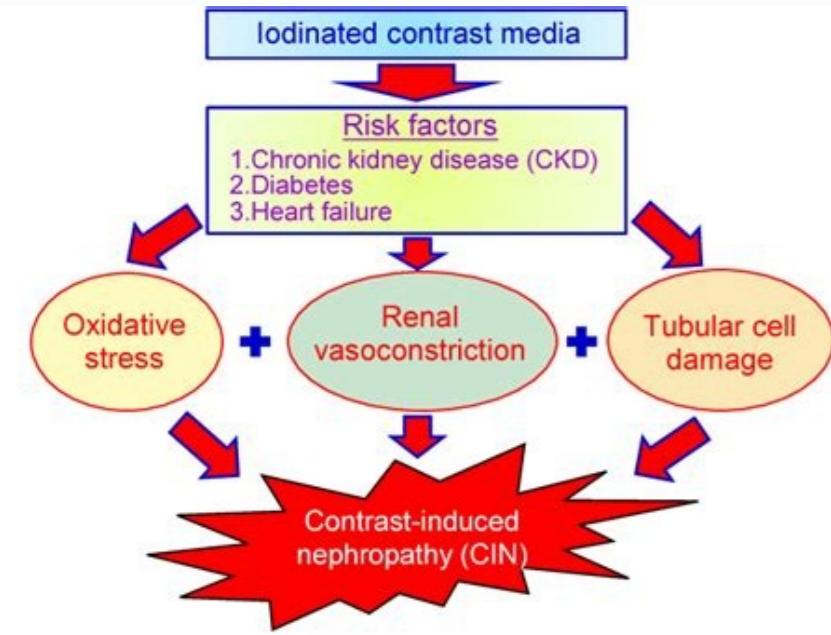
Trial registration: NCT01165567

Background
Contrast-induced nephropathy (CIN) is a common form of hospital-acquired acute renal failure (ARF) after coronary angiography (CAG) and percutaneous coronary intervention (PCI) and is associated with prolonged hospitalization and adverse clinical outcomes [1,2]. Patients undergoing PCI have a higher mortality rate if the nephropathy develops [3]. Although its incidence is low in patients with normal renal function, it can be much higher in those with renal insufficiency at baseline [4,5]. Adequate prophylaxis is needed to reduce the higher

Adequate prophylaxis is needed to reduce the higher morbidity and mortality associated with CIN in high-risk patients. A variety of therapeutic interventions, although the pathogenesis of this condition is not fully understood, it is most likely the result of renal ischemia and direct toxicity to tubular epithelial cells [13,14]. After contrast is injected, renal blood flow transiently increases and then decreases over a longer time suggesting that renal ischemia is a major factor in the pathogenesis of CIN [13]. Contrast agents reduce the

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don't go beyond the hospital results. A fourth randomized study looked at 71 patients at risk of a specialty so that they would not receive prophylaxis, but compared them with 67 patients at risk who received intravenous hydration³ one hour before contrast with sodium bicarbonate, which is different from the³ intravenous hydration of normal saline solution. To our knowledge, a randomized trial, apart from AMACING, has prospectively compared the intravenous hydration proposed by the guidelines with the intravenous hydration³ non-prophylaxis, in most of the³ population targeted by the guidelines. Another limitation is³ not all long-term creatinine values measured in the same laboratory. Both found significantly lower incidences of NIC/CI-AKI after prophylaxis (22/108 vs 38/10818 and 22/204 vs 43/204 []). Error bars show standard deviations. The estimated results of the linear mixed model with random intercept indicated that creatinine levels significantly increased over time in both groups, $\Delta \text{creatinine} = 0.682 \pm 0.4 \text{ mol/L}$ ($H_+ - H_0$; 95% CI -4.95 to $+3.59$; pA_cA_c² $\Delta \text{creatinine} = 4.95 \pm 0.4 \text{ mol/L}$). Table 3 provides incidences of major complications in the no prophylaxis (H_0) and standard prophylactic treatment (H_+) groups. eGFR was calculated with serum creatinine concentrations and the Modification of Diet in Renal Disease (MDRD) study equation as recommended by the same guidelines. Exclusion criteria were inability to obtain informed consent, eGFR < 60 years, history of dialysis, use of nephrotoxic medication, urological or nephrologic background, hypertension, vascular disease / PERIFICAL CARDIACE, MIGHTLY MYELOMA / LYLOMA Lymphoma Lymphoma Macictotabla. The data are N (%) or average (DE). Sijpkens y.w.j. Van Buren M. Renal decline more than 10 EGFR units; 3. There was a decrease in the renal function to TFE from 15 to 29 ml / min / 1,173 m² in 17 patients: in 8 of 292 patients (2.74%) of the H_0 group, and in 9 of 297 patients (3.03%) of group H_+ , with an absolute difference between the groups ($H_+ - H_0$) of 0.29% (95%). 2.65 to 3.24; $\Delta \text{creatinine} = 0.682 \pm 0.4 \text{ mol/L}$. The present article presents the long-term results. amacing is a phase 3, randomized, parallel group, open, non-inferiority group in patients with an estimated glomerular filtration rate [TFGE] $30 \pm 59 \text{ ml} / \text{min} / 1,73 \text{ m}^2$ in combination with risk factors, subjected to elective procedures per intravenously or intra-arterial iodinated contrast. Analysis includes all patients, including those in which the NIC / CI-AKI may have been unnoticed, and reflect the effectiveness of prophylaxis in the reduction of adverse outcomes post-contrasted. The retention of intravenous hydration Profilactica with normal saline solution is considered safe for elective patients with eGFR greater than 60 ml/min/1.73 m². With contrast-induced nephropathy (NIC), also known as contrast-induced acute nephropathy (CI-AKI), is marked by a decline in renal function typically occurring 2 to 5 days after intravenous or intra-arterial iodinated contrast material administration [, ,]. Prophylaxis is recommended by clinical practice guidelines to prevent such. These criteria corresponded to the criteria for identifying patients at-risk according to guidelines current at the time of inclusion [[23]Veligheids Management Systeem VMS veiligheidsprogramma: voorkomen van nierinsufficiëntie bij intravasculair gebruik van jodiumhoudende contrastmiddelen.]. 2 Kaplan-Meier survival analysis for the standard prophylactic treatment (H_+) and no prophylactic treatment (H_0) groups. Wang X. et al. Randomised trial of no hydration vs. ECN and JEW supervised the study. ECN gathered the data. Such trials evaluating the guidelines were non-existent before AMACING. Similar trials with much larger sample sizes would give a better estimate, but it is unlikely that these will be carried out, especially considering the logistic and financial requirements of such trials. A limitation of the AMACING trial is that post-contrast serum creatinine measurements were not available for all patients, but absence of serum creatinine values was unrelated to the study intervention. The aim of the study was to evaluate efficacy of prophylaxis according to clinical guidelines in the prevention of post-contrast adverse outcomes in elective patients with estimated glomerular filtration rate [eGFR] $30 \pm 59 \text{ ml} / \text{min} / 1.73 \text{ m}^2$ combined with risk factors for CIN/CI-AKI [[22]Nijssen E.C. Rennenberg R.J. Nelemans P.J. et al. Prophylactic hydration of renal function from intravascular iodinated contrast material in patients at high risk of contrast-induced nephropathy (AMACING): a prospective, randomised, phase 3, controlled, open-label, non-inferiority trial. Summary Full Text Full Text PDF PubMed Scopus (243) Google Scholar]. In the hydrated group, 52% received a short 48% bolus hydration protocol. 3) Observed mean serum creatinine and changes in serum creatinine in the standard prophylactic (H_+) and non-prophylactic (H_0) groups. RJR, GVO and PJN critically reviewed the report. We declare that there are no competing interests. AMACING is registered at ClinicalTrials.gov: NCT02106234. Of 28,803 patients at risk were identified. Four such trials were published in 2014 and 2015, comparing prophylactic intravenous hydration with a group not receiving any prophylaxis. [18]Luo Y. In addition, comparing patients with and without CIN/CI-AKI would involve performing an observational study within the RCT. One of these trials showed higher in-hospital mortality for the prophylaxis group (3/108 vs 10/108) [18]Luo Y. Therefore, when evaluating the efficacy of prophylaxis recommended by the guidelines, it is imperative to analyze the long-term mortality and renal function data of all patients with and without CIN/CI-AKI. We can have a 97.5% confidence interval that an increase in adverse clinical outcomes (no prophylaxis minus prophylaxis) will not exceed the upper limit of the confidence intervals. For the comparison of categorical variables between groups without prophylaxis and intravenously hydrated, the Chi-square test was used to test statistical differences. A non-inferiority design was based on the assumption that although post-contrast adverse events may occur more frequently in the absence of prophylaxis, intravenous hydration retention may have the advantage of reducing patient burden and medical care costs. The median follow-up time was 339 days post-contrast for the H_0 group (IQR 285-375), and 339 days post-contrast for the H_+ group (IQR 292-376). Judah or got funding. Randomization was stratified by diabetes (S_c vs no), renal function (eGFR 30 ± 44 vs. $45 \pm 59 \text{ ml} / \text{min} / 1.73 \text{ m}^2$), and administration of the Contrast contrast senoicacilpmoc ed %5,5 le atneuc ne eneit es is etnemlaicepse ,sixaliforp al reneter ed selaicnatsus .acitc;Äliforp asonevartni n³Äicatardih al ed otcefe led etrap anu ;Ärdnetnam es euq ertseumed es euq amrof ed esrinified nebed senegr;Äm sotsE .oyasne led soiradnuces secalnesed noreuf etsartnoc led s@Äupsed o±Äa la hufal ne oibmac y dadilatrom ,sisil;Äid secalnesed soL .a±Äeuqep anedac ed airunietorp noc ocitÄcomsalpofnil amofnil o elpitlÄm amoleim o ;2m ÄÄ37,1/nim/Lm ÄÄ44 y 03 ertne eGF o ;)sociit@Äruid o soedioretse on soirotamalfniitha socamr;Äf noc acixÄtorfen n³Äicacidem ;)lairetra dademrefne ;acaÄdrac aicneicifusni ralucusavoidrac ;serejum sal arap L/L ÄÄ63,0< y ,serbmoh sol arap L/L ÄÄ93,0< otircotameh ed serolav omoc adinifed aimena ;so±Äa ÄÄ57> dade(secirtcerid sal rop sodacificepe ogseir ed serotcaf sod sonem la o ,setebaid noc odanibmoc 2m ÄÄ37,1/nim/Lm ÄÄ95 y 54 ertne eGF nu naÄnet is n³Äisulcnii us arap selbigele nare setneicap soL)271(supocS deMbuP ferssorC.sisyhana-atem dna weiver citametsys a :yhargoigna yranoroc retfa semoctuo lacinilc esrevda fo ksir dna yrujni yendik etuca decudni-tsartnoC.la te .A.M gnnnaM .M.S leumaS .T.M semaj7 ,,[dadilatrom al y dadilibrom al ed otnemua nu a aicosa es orep ,soredarud setcefe rajed nis ,etnemaen;Ätnopse .setneidnepedni sartseum arap tnedutS ed t abeupr al etnaidem noraulave es saunitnog selbairav sal ed soidem serolav sol ne saicnerefid sal .] ,ralohcS elgoog)63(supocS deMbuP ferssorC.ortnec olos nu ne oirotaela oyasne nu :TS otnemges led n³Äicavale noc odracoim ed otralp otroc a sosrevda setneve sol le rop adicudni aÄtaporfen ed aicnedicni al ecuder arodaraper n³Äicatardih aL.la te .)ocits³Ängaid sv atsinoicnevreti(otneimidecorp ed opit le y ,)osonevartni sv n³Äges n³Äges ethnematcirtse³Änoicceles es GNICAMA oyasne le ne adiulcni n³Äicalbop al ,secirtcerid sal ed aicacife al erbos oyasne nu ed esratart la .ocitc;Äliforp otneimatart le e current guidelines criteria. Blinding patients or nursing and research staff³ not feasible due to the obvious difference in the treatment of prophylaxis and patients hydrated by intravenous pneumonia. 4.5%; Source: Stichting Kwaliteits (Bewaking Ziekenhuis Laboratory). Nine per cent of the³ population were hospitalized patients, and 10% EGFR

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