Using the CONSORT for Abstracts checklist: some examples

This is a series of slides providing illustrative examples of randomized trials using the CONSORT for Abstracts checklist.

These are well reported trials published prior to the publication of this checklist. The "before" and "after" examples have been used to illustrate how reporting could be enhanced by including additional items from the CONSORT for Abstracts checklist. They have been prepared in consultation with the trial authors.

These examples should be read in conjunction with the CONSORT for Abstracts explanation and elaboration publication.

BEFORE

Effectiveness of early switch from intravenous to oral antibiotics in severe community acquired pneumonia: multicentre randomised trial

Jan Jelrik Oosterheert, Marc J M Bonten, Margriet M E Schneider, Erik Buskens, Jan-Willem J Lammers, Willem M N Hustinx, Mark H H Kramer, Jan M Prins, Peter H Th J Slee, Karin Kaasjager, Andy I M Hoepelman

Objectives To compare the effectiveness of an early switch to oral antibiotics with the standard 7 day course of intravenous antibiotics in severe community acquired pneumonia.
Design Multicentre randomised controlled trial.
Setting Five teaching hospitals and 2 university medical centres in the Netherlands.
Participants 302 patients in non-intensive care wards with severe community acquired pneumonia. 265 patients fulfilled the study requirements.
Intervention Three days of treatment with intravenous antibiotics followed, when clinically stable, by oral antibiotics or by 7 days of intravenous antibiotics.
Main outcome measures Clinical cure and length of hospital stay.
Results 302 patients were randomised (mean age 69.5 (standard deviation 14.0), mean pneumonia severity score 112.7 (26.0)). 37 patients were excluded from analysis because of early dropout before day 3, leaving 265 patients for intention to treat analysis. Mortality at day 28 was 4% in the intervention group and 6% in the control group (mean difference 2%, 95% confidence interval -3% to 8%). Clinical cure was 83% in the intervention group and 85% in the control group (2%,-7% to 10%). Duration of intravenous treatment and length of hospital stay were reduced in the intervention group, with mean differences of 3.4 days (3.6 (1.5) *v* 7.0 (2.0) days; 2.8 to 3.9) and 1.9 days (9.6 (5.0) *v* 11.5 (4.9) days; 0.6 to 3.2), respectively.
Conclusions Early switch from intravenous to oral antibiotics in patients with severe community acquired pneumonia is safe and decreases length of hospital stay by 2 days.
Trial registration Clinical Trials NCT00273676.

Text highlighted in blue signifies where items are reported from the CONSORT for Abstracts checklist

Item	Reported
Title	✓
Authors contact details	
Trial design	
Methods	
Participants	✓
Interventions	✓
Objective	✓
Outcomes	✓
Randomization	
Blinding (masking)	
Results	
Number randomized	
Recruitment	
Number analysed	
Outcome	✓
Harms	
Conclusions	✓
Trial registration	✓
Funding	

Word count: 248

Oosterheert JJ, Bonten MJ, Schneider MM, Buskens E, Lammers JW, Hustinx WM, Kramer MH, Prins JM, Slee PH, Kaasjager K, Hoepelman AI. Effectiveness of early switch from intravenous to oral antibiotics in severe community acquired pneumonia: multicentre randomised trial. BMJ. 2006;333(7580):1193.

AFTER

Effectiveness of early switch from intravenous to oral antibiotics in severe community acquired pneumonia: multicentre randomised trial

Jan Jelrik Oosterheert, Marc J M Bonten, Margriet M E Schneider, Erik Buskens, Jan-Willem J Lammers, Willem M N Hustinx, Mark H H Kramer, Jan M Prins, Peter H Th J Slee, Karin Kaasjager, Andy I M Hoepelman

Correspondence to: i.m.hoepelman@umcutrecht.nl

Objectives Effectiveness of early switching to oral antibiotics compared with standard 7 day course of intravenous antibiotics in severe community acquired pneumonia.

Design Multicentre parallel randomised controlled, open label, trial. A central randomisation centre used computer generated tables to allocate treatments.

Setting Five teaching hospitals and 2 university medical centres in the Netherlands.

Participants 302 patients in non-intensive care wards with severe community acquired pneumonia. 265 patients fulfilled the study requirements.

Intervention Three days of treatment with intravenous antibiotics followed, when clinically stable, by oral antibiotics or by 7 days of intravenous antibiotics. Follow-up 28 days.

Main outcome measures Clinical cure and length of hospital stay.

Results 302 patients (early switch n=152; standard care n=150) were randomised (mean age 69.5 (standard deviation 14.0), mean pneumonia severity scoe 112.7 (26.0)). 37 patients were excluded from analysis because of early dropout before day 3, leaving 265 (n=132; n=133) patients for intention to treat analysis. Clinical cure was 83% in the intervention group and 85% in the control group (2%, -7% to 10%). Duration of intravenous treatment and length of hospital stay were reduced in the intervention group, with mean differences of 3.4 days (3.6 (1.5) *v* 7.0 (2.0) days; 2.8 to 3.9) and 1.9 days (9.6 (5.0) *v* 11.5 (4.9) days; 0.6 to 3.2), respectively. Mobility and other side effects were comparable across groups.

Conclusions Early switch from intravenous to oral antibiotics in patients with severe community acquired pneumonia is safe and decreases length of hospital stay by 2 days.

Trial registration Clinical Trials NCT00273676.

Funding Dutch Health Insurance Council, OG 99-64.

Text highlighted in red signifies where items have been added from the CONSORT for Abstracts checklist

Item	Reported
Title	✓
Authors contact details	✓
Trial design	✓
Methods	
Participants	✓
Interventions	✓
Objective	✓
Outcomes	✓
Randomization	✓
Blinding (masking)	✓
Results	
Number randomized	✓
Recruitment	✓
Number analysed	✓
Outcome	✓
Harms	✓
Conclusions	✓
Trial registration	✓
Funding	✓

Word count: 260

BEFORE

Effect of Pioglitazone Compared With Glimepiride on Carotid Intima-Media Thickness in Type 2 Diabetes
A Randomized Trial

Context Carotid artery intima-media thickness (CIMT) is a marker of coronary atherosclerosis and independently predicts cardiovascular events, which are increased in type 2 diabetes mellitus (DM). While studies of relatively short duration have suggested that thiazolidinediones such as pioglitazone might reduce progression of CIMT in persons with diabetes, the results of longer studies have been less clear.

Objective To evaluate the effect of pioglitazone vs glimepiride on changes in CIMT of the common carotid artery in patients with type 2 DM.

Design, Setting, and Participants Randomized, double-blind, comparator controlled, multicenter trial in patients with type 2 DM conducted at 28 clinical sites in the multiracial/ethnic Chicago metropolitan area between October 2003 and May 2006. The treatment period was 72 weeks (1-week follow-up). CIMT images were captured by a single ultrasonographer at 1 center and read by a single treatment-blinded reader using automated edge-detection technology. Participants were 462 adults (mean age, 60 [SD, 8.1] years; mean body mass index, 32 [SD, 5.1]) with type 2 DM (mean duration, 7.7 [SD, 7.2] years; mean glycosylated hemoglobin [HbA1c] value, 7.4% [SD, 1.0%]), either newly diagnosed or currently treated with diet and exercise, sulfonylurea, metformin, insulin, or a combination thereof.

Interventions Pioglitazone hydrochloride (15-45 mg/d) or glimepiride (1-4 mg/d) as an active comparator.

Main Outcome Measure Absolute change from baseline to final visit in mean posterior-wall CIMT of the left and right common carotid arteries.

Results Mean change in CIMT was less with pioglitazone vs glimepiride at all time points (weeks 24, 48, 72). At week 72, the primary end point of progression of mean CIMT was less with pioglitazone vs glimepiride (–0.001 mm vs +0.012 mm, respectively; difference, –0.013 mm; 95% confidence interval, –0.024 to 0.002; *P* = .02). Pioglitazone also slowed progression of maximum CIMT compared with glimepiride (0.002 mm vs 0.026 mm, respectively, at 72 weeks; difference, –0.024 mm; 95% confidence interval, –0.042 to –0.006; *P* = .008). The beneficial effect of pioglitazone on mean CIMT was similar across prespecified subgroups based on age, sex, systolic blood pressure, duration of DM, body mass index, HbA1c value, and statin use.

Conclusion Over an 18-month treatment period in patients with type 2 DM, pioglitazone slowed progression of CIMT compared with glimepiride.

Trial Registration clinicaltrials.gov Identifier: NCT00225264

Text highlighted in blue signifies where items are reported from the CONSORT for Abstracts checklist

Item	Reported
Title	✓
Authors contact details	
Trial design	✓
Methods	
Participants	✓
Interventions	✓
Objective	✓
Outcomes	✓
Randomization	
Blinding (masking)	✓
Results	
Number randomized	
Recruitment	✓
Number analysed	
Outcome	✓
Harms	
Conclusions	✓
Trial registration	✓
Funding	

Word count: 373

Mazzone T, Meyer PM, Feinstein SB, Davidson MH, Kondos GT, D'Agostino RB Sr, Perez A, Provost JC, Haffner SM. Effect of pioglitazone compared with glimepiride on carotid intima-media thickness in type 2 diabetes: a randomized trial. JAMA. 2006;296(21):2572-81.

http://jama.ama-assn.org/cgi/content/full/296/21/2572

AFTER

Effect of Pioglitazone Compared With Glimepiride on Carotid Intima-Media Thickness in Type 2 Diabetes

A Randomized Trial

Correspondence to: tmazzone@uic.edu

Context Carotid artery intima -media thickness (CIMT) is a marker of coronary Atherosclerosis,predicting cardiovascular events, which are increased in type 2 diabetes mellitus (DM).

Objective Effect of pioglitazone versus glimepiride on changes in CIMT of the common carotid artery in patients with type 2 DM.

Design, Setting, and Participants Randomized, double-blind, comparator-controlled, multicenter trial in patients with type 2 DM conducted in 28 clinical sites in the multiracial/ethnic Chicago metropolitan between October 2003 and May 2006. The treatment period was 72 weeks (1 week follow-up). CIMT images were captured by a single ultrasonographer at 1 center and read by a single treatment-blinded reader using automated edge-detection technology. Randomized participants were 462 adults (pioglitazone n=232; glimepride n= 230) (mean age, 60 [SD, 8.1] years; mean body mass index, 32 [SD, 5.1]) with type 2 DM (mean duration, 7.7 [SD, 7.2] years; mean glycosylated hemoglobin [HbA1c] value, 7.4% [SD, 1.0%]), either newly diagnosed or currently treated with diet and exercise, sulfonylurea, metformin, insulin, or a combination thereof.

Interventions Pioglitazone hydrochloride (15-45 mg/d) versus glimepiride (1-4 mg/d).

Main Outcome Measure Absolute change from baseline to final visit in mean posterior-wall CIMT of the left and right common carotid arteries.

Results 458 participants were analysed. Mean change in CIMT was less with pioglitazone (n=230) vs glimepiride (n=228) at all time points (weeks 24, 48, 72). At week 72, the primary end point of progression of mean CIMT was less with pioglitazone vs glimepiride (–0.001 mm vs +0.012 mm, respectively; difference, –0.013 mm; 95% confidence interval, –0.024 to –0.002; *P* = .02). Pioglitazone also slowed progression of maximum CIMT compared with glimepiride (0.002 mm vs 0.026 mm, respectively, at 72 weeks; difference, –0.024 mm; 95% confidence interval, –0.042 to –0.006; *P* = .008). The beneficial effect of pioglitazone on mean CIMT was similar across prespecified subgroups based on age, sex, systolic blood pressure, duration of DM, body mass index, HbA1c value, and statin use. Twenty-six pioglitazone-treated participants discontinued treatment due to adverse events compared to 19 glimepride treated participants.

Conclusion Over an 18-month treatment period in patients with type 2 DM, pioglitazone slowed progression of CIMT compared with glimepiride.

Trial Registration clinicaltrials.gov Identifier: NCT00225264

Funding National Heart and Blood Institute grant K25 HL68139

Text highlighted in red signifies where items have been added from the CONSORT for Abstracts checklist

Item	Reported
Title	✓
Authors contact details	✓
Trial design	✓
Methods	
Participants	✓
Interventions	✓
Objective	✓
Outcomes	✓
Randomization	*
Blinding (masking)	✓
Results	
Number randomized	✓
Recruitment	✓
Number analysed	✓
Outcome	✓
Harms	✓
Conclusions	✓
Trial registration	✓
Funding	✓

* not reported in the original article

Word count: 367

http://jama.ama-assn.org/cgi/content/full/296/21/2572

BEFORE

Effect of mammographic screening from age 40 years on breast cancer mortality at 10 years' follow-up: a randomised controlled trial

Background The efficacy of screening by mammography has been shown in randomised controlled trials in women aged 50 years and older, but is less clear in younger women. A meta-analysis of all previous trials showed a 15% mortality reduction in invited women aged 40–49 years at study entry, but this finding could be due in part to screening of women after age 50 years. The Age trial was designed to study the effect on mortality of inviting women for annual mammography from age 40 years.

Methods 160 921 women aged 39-41 years were randomly assigned in the ratio 1:2 to an intervention group of annual mammography to age 48 years or to a control group of usual medical care. The trial was undertaken in 23 NHS breast-screening units in England, Wales, and Scotland. The primary analysis was based on the intention-to-treat principle and compared mortality rates in the two groups at 10 years' follow-up. This study is registered as an International Standard Randomised Controlled Trial, number ISRCTN24647151

Findings At a mean follow-up of 10·7 years there was a reduction in breast-cancer mortality in the intervention group, in relative and absolute terms, which did not reach statistical significance (relative risk 0·83 [95% CI 0·66–1·04], p=0·11; absolute risk reduction 0·40 per 1000 women invited to screening [95% CI −0·07 to 0·87]). Mortality reduction adjusted for non-compliance in women actually screened was estimated as 24% (RR 0·76, 95% CI 0·51–1·01).

Interpretation Although the reduction in breast-cancer mortality observed in this trial is not significant, it is consistent with results of other trials of mammography alone in this age-group. Future decisions on screening policy should be informed by further follow-up from this trial and should take account of possible costs and harms as well as benefits.

Text highlighted in blue signifies where items are reported from the CONSORT for Abstracts checklist

Item	Reported
Title	✓
Authors contact details	
Trial design	✓
Methods	
Participants	✓
Interventions	✓
Objective	✓
Outcomes	✓
Randomization	
Blinding (masking)	
Results	
Number randomized	✓
Recruitment	✓
Number analysed	
Outcome	✓
Harms	
Conclusions	✓
Trial registration	✓
Funding	

Word count: 295

Moss SM, Cuckle H, Evans A, Johns L, Waller M, Bobrow L; Trial Management Group. Effect of mammographic screening from age 40 years on breast cancer mortality at 10 years' follow-up: a randomised controlled trial. Lancet. 2006;368(9552):2053-60.

AFTER

Effect of mammographic screening from age 40 years on breast cancer mortality at 10 years' follow-up: a randomised controlled trial

Correspondence to: sue.moss@icr.ac.uk

Background The efficacy of screening by mammography has been shown in randomised controlled trials in women aged 50 years and older, but is less clear in younger women.

Objective To assess the effect on mortality of inviting women for annual mammography from age 40 years.

Methods 160 921 women aged 39-41 years were randomly assigned in the intervention group (n=53 914) of annual mammography to age 48 years or to a control group (n=107 007) of usual medical care. The trial was undertaken in 23 NHS breast-screening units in England, Wales, and Scotland. Randomization and allocation to trial group were carried out by a central computer system. The primary analysis was based 160 840 participants, (n=53 884; n=106 956), comparing mortality rates in the two groups at 10 years' follow-up.

Findings Mean follow-up of 10·7 years showed a reduction in breast-cancer mortality in the intervention group, in relative and absolute terms, but did not reach statistical significance (relative risk 0·83 [95% CI 0·66–1·04], p=0·11; absolute risk reduction 0·40 per 1000 women invited to screening [95% CI −0·07 to 0·87]). Mortality reduction adjusted for non-compliance in women actually screened was estimated as 24% (RR 0·76, 95% CI 0·51–1·01).

Interpretation Although the reduction in breast-cancer mortality observed in this trial is not significant, it is consistent with results of other trials of mammography alone in this age-group. Future decisions on screening policy should be informed by further follow-up from this trial and should take account of possible costs and harms as well as benefits.

Trial registration ISRCTN24647151.

Funding UK Medical Research Council, Cancer Research UK, US National Cancer Institute.

Text highlighted in red signifies where items have been added from the CONSORT for Abstracts checklist

Item	Reported
Title	✓
Authors contact details	✓
Trial design	✓
Methods	
Participants	✓
Interventions	✓
Objective	✓
Outcomes	✓
Randomization	✓
Blinding (masking)	*
Results	
Number randomized	✓
Recruitment	✓
Number analysed	✓
Outcome	✓
Harms	✓
Conclusions	✓
Trial registration	✓
Funding	✓

* not reported in the original article

Word count: 269