Abstract content and format

C= Clinical Science, B= Basic Science

Title

C: if RCT, identify the trial as being randomised in title
B: if randomised, identify the trial as such in title

maximum number of words: 25

Study question

C&B: A single sentence, limited to the primary objective of the study (do not include secondary questions)

maximum number of words: 25

Summary answer

C&B: The main conclusion. A single sentence, this should be limited to the primary results of the study, without any discussion of their implications

maximum number of words: 25

What is known already

C&B: One or two short sentences

maximum number of words: 100

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Study design, size, duration

C: RCT, cohort study, case control study, cross sectional study, diagnostic test; sample size calculation; total number of subjects involved; time period in which study was performed

✓ If RCT: briefly describe size and duration, intervention(s), blinding, randomization procedure, allocation oncealment

✓ If cohort study: briefly describe size and duration, prospective/retrospective, (lost to) follow-up, attrition

✓ If case control study: briefly describe number of cases and controls, duration, exposures

✓ If cross sectional study: briefly describe size

✓ If diagnostic test study: briefly describe size and duration, reference standard and comparator/index test, blinding

B: Cross sectional – control versus treatment, longitudinal –time-course, age-course. Numbers of treated/controls, treatment duration, sampling procedures

maximum number of words: 75

Participants/materials, setting, methods

C: matching criteria (for matched studies), numbers exposed/unexposed, numbers of controls per case, distribution of severity of disease in those with target condition

B: General approach used eg cell/tissue culture/transfection, animal treatments/models, transgenesis. Species, ages, gender, cell type. Methods and endpoints used – eg hormone, cytokine, growth factor measurements, cell numbers/proliferation, tissue morphology/composition, FACS, immunohistochemistry, Westerns, quantitative PCR, FISH

maximum number of words: 75

Main results and the role of chance

C: ✓ If RCT: include absolute event rates for primary outcome(s) among experimental and control groups, p value(s) and confidence intervals, relative risk reduction, number needed to treat or harm.

✓ If cohort study: include absolute event rates over time in exposed and unexposed, relative risk reduction.

✓ If case control study: include odds ratio for strength of association between exposure and outcome.

✓ If cross sectional study: include response rate

✓ If diagnostic test study: include sensitivity, specificity, positive and negative predictive values, likelihood ratios. Number needed to screen (if screening study)

B: P values, biological gradient, repeatability/robustness, mechanisms identified/involved

maximum number of words: 200

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Limitations, reasons for caution

C: bias, confounding, power
B: Descriptive, only in vitro, cell transfection, shown only in one species, technical limitations and reasons for caution, cell/animal lethality in a knock-out, disease- or cell-specificity

maximum number of words: 50

Wider implications of the findings

C: generalisability to other populations, agreement/disagreement with literature, resolution of previous disparity, new insights
B: Agreement/disagreement with literature, resolution of previous disparity, new insights/mechanisms in disease(s), new therapeutic potential, cell-, species- gender-, or age-implications, relevance to other systems

maximum number of words: 50

Study funding/competing interest(s)

C&B – select one (or more) of the listed options and specify

Trial registration number

C: if the study is an RCT, a trial number from an ICMJE-recognised trial registry (see http://www.icmje.org/faq.html) must be included
B: a trial registration number is only required for clinical trials

maximum number of words: 25