

# CREDIBILITY OF SUBGROUP CLAIMS IN HAEMATOLOGY CLINICAL TRIALS

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## Background and importance

Interpretation of subgroup analysis is potentially important for treatment decisions in medical practice.

## Aim and objectives

The aim of this study is to assess the credibility of subgroup claims in haematology RCT

## Material and methods

- **Design:** Systematic review of Hematology phase III RCT
- **Period of study:** January 2013-October 2019
- Claims of subgroup effect were classified: Strong claim, claim of a likely effect or suggestion of a possible effect based on **Sun et al 2009 classification**.
- “the 10 criteria for assessing the credibility of a subgroup claim” by **Sun et al 2012** were applied.

## Results

- 98 studies reported **subgroup analyses**.
- 24 RCT reported **46 claims of subgroup effect**.
- 44 were claims for the **primary outcome**
- 34/44 claims for the primary outcome, **met 4 or fewer of the 10 credibility criteria**.

Proportion of claims meeting subgroup criteria for primary outcomes

Criteria	Strong claim (n = 25)	Claim of likely effect (n = 2)	Suggestion of possible effect (n = 17)	Total (n = 44)
Is the subgroup variable a characteristic measured at baseline or after randomisation? *	22 (88%)	2 (100%)	14 (82.35%)	38 (86.36%)
Was the subgroup variable a stratification factor at randomization?	12 (48%)	1 (50%)	2 (11.76%)	15 (34.09%)
Was the subgroup hypothesis specified a priori?	7 (28%)	0	4 (23.53%)	11 (25%)
Was the subgroup effect one of a small number of hypothesised effects tested (</= 5)?	6 (24%)	1 (50%)	10 (58.82%)	17 (38.63%)
Was the interaction test significant (P <0.05)?	10 (40%)	0	8 (47.06%)	18 (40.91%)
Is the significant subgroup effect independent, if they were multiple significant interactions? *	13 (52%)	1 (50%)	12 (70.58%)	26 (59.09)
Was the direction of the subgroup effect correctly prespecified?	0	0	0	0
Was the subgroup effect consistent with evidence from previously related studies?	7 (28%)	1 (50%)	3 (17.65%)	11 (25%)
Was the subgroup effect consistent across related outcomes?	6 (24%)	0	4 (23.53%)	10 (22.72%)
Is there indirect evidence that supports the hypothesised interaction (biological rationale)?	4 (16%)	0	4 (23.53%)	8 (18.18%)

## Conclusion and relevance

- Subgroup claims reported in hematology RCT lack of credibility, even when claims are strong.
- Subgroup analysis should be carried out due to the potential information they can provide