**Title**

A descriptive epidemiological study comparing occurrence of adverse events in clinical trials carried out in older people exclusively, and in the general population

**Background**

Clinical Trials are considered the best evidence for guiding medical treatments and interventions. We have identified in previous work that whilst older people are under-represented in clinical trials, it seems likely that clinical trials carried out exclusively in older people are representative of older people generally. We wish to expand on and clarify this work by specifically looking at adverse events in clinical trials carried out in older people and comparing this to the generaI population .It has been suggested that adverse drug reactions may be more severe and frequent in the elderly, although interestingly there is speculation that elderly people may be less likely to report these. (1) However, the work we have done to date does not support that statement. Due to the burden of co-morbidity in older patients, it is difficult to clarify whether adverse events are due to trial medications, which leads to the rationale for designing clinical trials specifically for this group. (2)

***An adverse event*** (AE) is any unfavourable and unintended sign, (including a laboratory finding) symptom or disease temporarily associated with the use of a medical treatment that may or may not be considered related to the medical treatment or procedure (3). They could occur in either the intervention or control arm in a clinical trial. This is detailed in the safety data of the trial report and in the clinical trial context is not necessarily a consequence of trial treatment.

***A Serious adverse event*** (SAE) is as an adverse event which is life threatening, requires initial or prolonged hospitalization, leads to disability or permanent damage or requires intervention to prevent impairment or damage. SEAs can occur in either the intervention or control group in a clinical trial. (4) This will de detailed in the safety data of the study report.

***Death*** is defined as death for any reason during the study period of the clinical trial. This is detailed in the safety data of the trial, but may also be listed as a trial outcome in some cases.

Thus in this study we aim to look at the comparison of adverse events, serious adverse events and death in clinical trials carried out exclusively in older people and those carried out in adults of all ages. We wish to use this data to assess applicability of clinical trials carried out exclusively in older people to the general population of older people. We will do this using drugs acting on the renin angiotensin aldosterone system as an exemplar.

**Aims**

To compare the adverse event rate of clinical trials carried out in older people to those carried out in adults of all ages and ultimately to the population of older adults, to assess the representativeness of clinical trial data to the general population of older adults.

**Objectives**

* To compare the rate of adverse events, serious adverse events and deaths in clinical trials carried out in older people and clinical trials carried out in the general population
* To compare the rate of adverse events, serious adverse events and deaths in clinical trials carried out in older people with the general population of older adults

**Methods**

A retrospective collection of data regarding baseline characteristics and adverse events of clinical trials carried out in older people exclusively with regard to drugs acting on the renin angiotensin aldosterone system (RAAS) to treat hypertension. A similar collection shall be carried out on clinical trials of all ages regarding drugs acting on the RAAS to treat hypertension in adults of all ages.

Subsequently the adverse event data collected from the clinical trial population of patients included in trials of drugs acting on the RAAS to treat hypertension, shall be compared to the general population of adults (older and all ages) taking medications acting on the RAAS to treat hypertension. This shall be done using SAIL data, which give a representation of the population of Wales

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