Regional variation in clinical trials participation for ovarian cancer in the UK

Introduction

Results from previous analyses since 2013/14 have identified significant regional variation in trials participation for ovarian cancer patients, with a 5.5-fold difference in recruitment between regions in 2015/16. This analysis describes the regional variation observed in 2013/14 and 2016/17.

Key findings

Interventional trials:
• Overall recruitment to interventional trials has increased from 396 (2013/14) to 793 (2015/16), although there was a decrease to 484 in 2016/17.
• Feedback from the regions was collected in 2016, describing the key challenges for recruiting to clinical trials.

Observational trials:
• Overall recruitment to observational trials has increased from 6/9 (2012/13) to 7/9 (2015/16), with a 7.5-fold difference in recruitment between the top and bottom regional quartiles.

Method

Data on clinical trial participation was kindly provided by the NIHR Clinical Research Network (CRN):
• Data describing participation in observational and interventional trials in ovarian cancer (2012/13 and 2016/17)
• Recruitment was analysed in relation to population and number of cases of ovarian cancer in each region

Results

Recruitment to clinical trials (UK) in ovarian cancer since 2001 — Observational and interventional

Factors that challenged recruitment

Staff shortages, particularly Research Nurses:
• This challenge was cited the most frequently
• Research nurse cover fluctuates a lot, and directly relates to successful study recruitment
• Vaccinations in key research posts lead to difficulties opening trials in a timely manner
• "Some sites are more research nurse driven, and the trust does not want to replace them because of financial constraints so the trial portfolio and recruitment suffer"*

Clinical service commitments:
• Busy job plans and heavy clinical workloads hinder participation in clinical trials
• Clinical service commitments are a barrier to recruitment
• "We have limited capacity, and it is difficult to find appropriate patients that meet the eligibility criteria"*

Factors that helped recruitment

• Groups that developed a more cohesive approach when choosing trials, ensuring that the bigger national studies were covered
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• A keen Principal Investigator who has the time (in job plan) to devote to recruiting and recruiting in trials, including an assistant dedicated to research
• Adequate research nurse cover
• An MUS Trust that is supportive of research research, funding the posts required to run trials properly

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Trial design and referral:
• Many ovarian cancer studies are phase II and smaller hospital sites may prefer not to open these in order to recruit 3-5 patients only
• More trials have specific eligibility criteria seeking a subpopulation of patients eg histological subtype/BRCA mutation status specific prior therapies
• Increasing numbers of older women of poor performance status who are not eligible for many trials – area of current need
• Regions send patients to London to be considered for phase I/II trials if they do not have anything available locally. Therefore, the accrual at London centres will be boosted by patients being referred from other areas

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Recruitment to clinical trials (2013/14 to 2016/17) — by region

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