Results of clinical trial on the use of topical treatments in Squamous cell carcinoma prevention

Background

Squamous cell carcinoma (SCC) is a common skin cancer in the UK, with approximately 30,000 new cases each year. SCC rates are increasing rapidly and many people affected will develop multiple SCC, usually requiring repeated surgical procedures. SCC also causes more than 20% of skin cancer-related deaths and is numerically and economically a major burden to the NHS.

Actinic Keratoses (AK) are common skin lesions, estimated to affect almost a quarter of the UK population over 60y. They are potentially precancerous lesions for SCC. Although only a fraction of individual AK progress to SCC, there is a close relationship between AK numbers and SCC risk. Surprisingly, this possibility has never been properly tested until now. Organ transplant patients are an ideal patient group in whom to investigate this hypothesis as they have a very high (100-fold increased) risk of developing SCC and show an accelerated progression from AK to SCC.

The clinical trial

The National Institute for Health Research (NIHR) via the Research for Patient Benefit programme funded the SPOT trial which was a multicentre, randomised, three arm, phase II, feasibility study comparing topical treatment of AKs.

The Sponsor of the trial was Queen Mary University of London. The trial was coordinated by the CRCTU, University of Birmingham, according to the CRCTU's standard operating procedures.

In this study, 40 transplant patients were recruited into one of 3 groups; either one of 2 commonly used cream treatments for AK (5-fluorouracil or imiquimod) or a sunscreen-only control group.

Outcome

The results showed in accordance with the key feasibility criteria, that it was feasible to proceed to a phase III randomised controlled trial. This has potential health and cost benefits for the NHS.

What does this mean?

There are potential benefits to the public and NHS in defining an effective preventative approach to cSCC management (in addition to sun avoidance) in terms of reduced illness, rates of death and healthcare costs. This study was the first step in this, paving the way for further research. Implementation of the resulting research findings will be a priority for Skin Cancer Services throughout the NHS, given the very common nature and escalating incidence of AK and cSCC.

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