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San Antonio Breast Cancer Symposium Abstract
Ongoing Clinical Trial

PRIMROSE: A BCTRCG prospective study of treatment and outcomes related to CNS disease secondary to breast cancer in the UK

VWT Cheng[1], HS McKenzie[2], A Kwan[3], A Konstantis[4], R Ma[5], PJ Teo[6], A Fitzpatrick[7], S Mehta[8], A Mukhopadhyay[9] & C Palmieri[10] on behalf of the PRIMROSE study group

[1]Leeds Cancer Centre, Leeds, [2]University of Southampton, Southampton, [3]University of Sheffield, Sheffield, [4]The Princess Alexandra NHS Trust, Harlow [5]Oxford University Hospitals NHS Trust, Oxford, [6]Worcestershire Acute Hospitals NHS Trust, Worcester, [7]Institute of Cancer Research, London, [8]Clatterbridge Cancer Centre NHS Foundation Trust, Wirral, [9]University of Glasgow, Glasgow, [10]University of Liverpool, Liverpool

Introduction

Breast cancer brain metastasis (BCBM) is a particular feature of HER2-positive and triple negative breast cancer (BC) and is becoming more common. This reflects the improved survival of patients living with metastatic breast cancer as well as increased cross-sectional imaging of the central nervous system with magnetic resonance imaging (1). The development of BCBM on the background of adequately controlled extracranial disease is an increasingly prevalent clinical scenario. BCBM causes significant morbidity and mortality; unfortunately the efficacy of systemic treatment is extremely limited and, at present, no systemic therapies are specifically approved for the treatment of BCBM (2). Basic and translational research to understand the pathophysiology of BCBM remains limited by a lack of access to annotated clinical material. Such research is needed if preventative and novel treatment strategies are to be developed. Moreover, there is currently a lack of basic contemporaneous information regarding the incidence and management of BCBM in the UK, how it may vary across the country and its impact on patient outcomes. Finally, clinical studies have been hampered by a lack of a central resource to aid feasibility work and to identify potentially eligible patients.

Study design

PRIMROSE will use the trainee collaborative model to establish an observational prospective UK cohort of newly diagnosed BCBM. Data collected will include routine clinico-pathological information, prior adjuvant and metastatic treatment as well as BCBM-related information including presentation, management and outcome. Anonymised data will be collated in a secure central REDCap database. All hospitals in the UK will be eligible to register patients driven by trainees from all specialties via the UK Breast Cancer Trainees Research Collaborative Group (BCTRCG) network.

Eligibility criteria

Inclusion criteria: male or female patients aged ≥16 years of age with histologically and/or cytologically confirmed BC with involvement of the brain parenchyma. There are no formal exclusion criteria. Patients with leptomeningeal disease will be registered with data being collected in a separate project (PRIMROSE-LMD).

Aims

The overarching objectives include defining the prevalence, management and outcome of BCBM in the UK.

Endpoints

***Primary Endpoint:** Overall survival from initial diagnosis of CNS involvement. **Secondary Endpoints will include:** 1**.** Time to initial CNS involvement from initial diagnosis of MBC; 2. Therapeutic interventions for management of CNS disease; 3. Time to intracranial tumour progression (for each line of therapy given for CNS disease); 4. Overall survival from MBC diagnosis; 5. Cause of death: progressive CNS disease versus progressive disease at other sites.
**Information will be presented for the whole cohort as well as by breast cancer subtype*

Patient accrual

Patient accrual is due to commence in July 2019 and continue will for 2 years in the first instance. There is no predefined target accrual.

Contact information

Study lead: Prof Carlo Palmieri; c.palmieri@liverpool.ac.uk

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