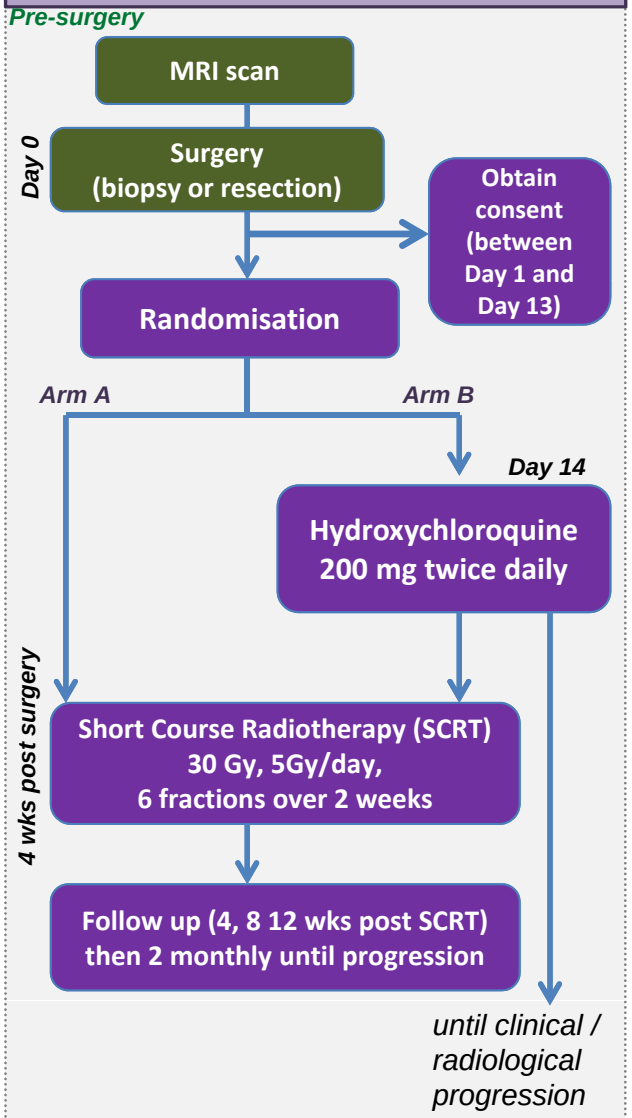
HCQ

A randomised phase 2 trial investigating the additional benefit of hydroxychloroquine (HCQ) to short course radiotherapy (SCRT) in patients aged 70 years and older with high grade gliomas (HGG)

Cancer Research UK and UCL Cancer Trials Centre

Trial Schema



Patient Eligibility

Inclusion Criteria

- ✓M/F patients ≥ 70 years
- ✓Histological diagnosis of HGG
- ✓Life expectancy of > 2 months
- ✓ECOG PS 0 or 1
- ✓MMSE scores ≥ 17
- ✓Absolute neutrophil count ≥ 1.5 x 10^9/L
- ✓Platelet count ≥ 100 x 10^9/L
- ✓Bilirubin ≤ 25.6 µmol/L
- ✓Creatinine ≤ 2 x ULN
- ✓ALT and AST ≤ 4 x ULN
- ✓Ready to start RT within 4 wks of surgery
- ✓Written Informed Consent

Exclusion Criteria

- ×Concurrent **psoriasis** unless the disease is well controlled
- ×**Prior macular degeneration or diabetic retinopathy**
- ×Concurrent serious infection or medical illness that would preclude study therapy
- ×Another malignancy within the past 5 years except for curatively treated carcinoma in situ or basal cell carcinoma of the skin
- ×**Porphyria**
- ×**Glucose- 6 phosphate dehydrogenase (G6PD) deficiency**
- ×**Documented side effects to chloroquine or related agents.**
- ×Alcoholic liver disease
- ×Any other concurrent severe/uncontrolled medical conditions
- ×Currently taking **amiodarone**
- ×Prior radiotherapy, chemotherapy, immunotherapy, biologic agents or hormonal therapy for brain tumour
- ×Prior polifeprosan 20 w/ carmustine implant or GliaSite® brachytherapy
- ×Concurrent cytochrome P450 enzyme-inducing anticonvulsant drugs
- ×Other concurrent chemotherapeutic or IMP for this cancer
- ×A history of a psychological illness or condition that in the opinion of the investigator may adversely affect **compliance with study medication**

Things to look out for…

- ➢**IMP: Hydroxychloroquine (hospital stock)**
- ➢**Visual assessment by ophthalmologist prior to commence of hydroxychloroquine, 12 week, 6 and 18 months after completion of SCRT in Arm B patients**
- ➢**Progression reporting per modified RANO criteria (Wen 2010)**
- ➢**Post-op and F-U MRI (12 wks post completion of SCRT) to be reported**
- ➢**No dose modification**
- ➢**IMP to be discontinued if patients develop vision problems/haematological toxicities**

Contacts

Cancer Research UK and UCL Cancer Trials Centre

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Trial Endpoints

Primary Endpoint
o 1 year survival

Secondary Endpoints
o Toxicities
o Cause specific survival
o Progression free survival
o QoL
o Steroid dependence