



MRC
Clinical
Trials Unit



Supported by



OCTOPUS Participant Information Sheet – Visit information leaflet

This information is extra to the Octopus Participant Information Leaflet. It will provide you further information on the visits that are needed for Octopus, including what assessments will take place, when they will occur and approximately how long they will take. If you would like further information about the Octopus study, please discuss any queries with your study doctor or nurse.

Name and Timing of Visit	What will happen?	Where will it happen?	How much time will it take? (approx.)
Screening	<ul style="list-style-type: none"> Information on Octopus and Consent form signing Physical Examination and measurements Assessment of MS disability (EDSS) Information collected on <ul style="list-style-type: none"> Medical and MS history Medications being taken – bring a list and any health supplements including vitamins Demographic data including for Equality, diversity, and inclusion Magnetic Resonance Imaging (MRI) Scan Blood tests Urine tests Pregnancy test (if required) 	Hospital Clinic	1 hour plus an MRI scan (The MRI scan visit may be on a separate date, and you can expect this to take up to 60 minutes)
Randomisation – Month 0	<ul style="list-style-type: none"> Information about your general wellbeing Physical assessments to assess your neurological system including strength, co-ordination, walking and tests on arm function. Assessment of MS disability (EDSS) Questionnaires about your pain, fatigue, and quality of life Information collected on: <ul style="list-style-type: none"> Medications being taken Pregnancy test (if required) Blood draw for extra sample collection (optional and only at selected sites) Final check to confirm it is safe and participant can take part in the trial Randomisation and allocation of treatment Prescribe Octopus treatment (you should start taking your treatment within 2 weeks of being randomised) 	Hospital Clinic <i>Please note some assessments may be done at the screening visit and the research team may call you to confirm you are happy to take in the trial before you are allocated your treatment</i>	1-2 hours

Name and Timing of Visit	What will happen?	Where will it happen?	How much time will it take? (approx.)
One Month (Week 4)	<ul style="list-style-type: none"> • Information about your general wellbeing and health check • Information collected on: <ul style="list-style-type: none"> ○ Number of capsules taken ○ Medications being taken ○ Any side effects you may be having • Blood tests • Urine tests • Weight (if required) • Pregnancy test (if required) • Prescription of Octopus treatment and adjustment of number of capsules (if required) 	Hospital Clinic	One hour
For 4 weeks after each hospital visit	<ul style="list-style-type: none"> • Complete Diary card to record number of capsules taken 	At home	Up to 5 minutes each day
At 3 months (Week 12)	<ul style="list-style-type: none"> • Information collected on: <ul style="list-style-type: none"> ○ General wellbeing ○ Number of capsules taken ○ Medications being taken ○ Any side effects you may be having • Blood tests at GP or hospital clinic • Weight at GP or hospital clinic (if required) • Pregnancy test at GP or hospital clinic (if required) • Urine tests at home or hospital clinic • Prescription of Octopus treatment and adjustment of number of capsules to take (if required) 	Telephone call (at home) with visit to GP or hospital clinic for blood tests	Up to 30 minutes
6 months (Week 26) onwards and every 6 months afterwards, up to 5 years	<ul style="list-style-type: none"> • Information about your general wellbeing • Information collected on: <ul style="list-style-type: none"> ○ General wellbeing ○ Number capsules taken ○ Medications being taken ○ Any side effects you may be having • Blood and urine tests • MRI scan (at month 6, 18 and 24 only) • Physical assessments to assess your neurological system including strength, co-ordination, walking and tests on arm function. • Assessment of MS disability (EDSS) • Questionnaires about your pain, fatigue, and quality of life • Weight (if required) • Pregnancy test (if required) 	Hospital clinic	<p>1-2 hours plus an MRI scan (up to 60 minutes).</p> <p>Please note the MRI scan will only be at months 6, 18 and 24 only.</p>

Name and Timing of Visit	What will happen?	Where will it happen?	How much time will it take? (approx.)
	<ul style="list-style-type: none"> Blood draw for sample collection (optional and only at selected sites) Prescription and adjustment of number of capsules if required 		
Halfway between 6 monthly hospital visits (e.g. at 9 months)	<ul style="list-style-type: none"> Urine test at home Reporting results to research team via agreed telephone call Provide further urine samples to hospital (if required). 	At home and telephone call	Up to 15 minutes (more if required)
When finished treatment – 6 monthly up to the 5 years	<ul style="list-style-type: none"> Information collected on: <ul style="list-style-type: none"> General wellbeing Medications being taken Physical assessments to assess your neurological system including strength, co-ordination, walking and tests on arm function. Assessment of MS Disability (EDSS) Questionnaires about your pain, fatigue, and quality of life Blood draw for sample collection (optional and only at selected sites) 	Hospital Clinic	Up to one hour

This information should be used with the Octopus Participant information sheet. If you would like further information about the Octopus study, information, please discuss any queries with your study doctor or nurse.

Name of doctor or nurse

Hospital Department

Hospital

Address; Address

Tel: 01234 XXX XXX

Thank you for taking the time to read this information and for considering taking part in Octopus. Please feel free to keep this information sheet.