Supplementary Information

Methods

1. Study sites (all northern part of Germany)

Site		Principal Investigator
01	NeuroCure Clinical Research Center, Charité – Universitätsmedizin Berlin, Charitéplatz 1, 10117 Berlin	PD Dr. J. Dörr
02	Private Neurologist, Berlin	Dr. E. Becker
03	Private Neurologist, Berlin	Dr. B. Brockmeier
04	Private Neurologist, Berlin	Dr. K. Anvari
05	Klinik für Neurologie, Alexianer St. Josefs Krankenhaus Potsdam, Allee nach Sanssouci 7, 14471 Potsdam	PD Dr. O. Hoffmann
06	Klinik für Neurologie, Krankenhaus Martha-Maria Halle-Dölau gGmbH, Röntgenstraße 1, 06120 Halle	Dr. F. Hoffmann
07	Kliniken für Neurologie Teupitz/Lübben, Asklepios Fachkliniken Brandenburg GmbH, Buchholzer Str. 21, 15755 Teupitz	Prof. Dr. J. Faiss

2. Inclusion and exclusion criteria

2.1. Inclusion

- Written informed consent
- Age 18 to 65 (at randomization)
- Multiple sclerosis according to revised McDonald criteria (2005) or clinically isolated syndrome (CIS)

- Relapsing remitting disease course
- No relapse within 30 days prior to randomization
- Expanded disability status scale (EDSS) ≤ 6.0
- Continuous treatment with interferon-β1b for at least 3 months (at randomization)
- Exclusion of pregnancy and reliable contraception in women of childbearing potential (Pearl index <1)

2.2. Exclusion

- Any other disease courses than relapsing remitting
- Any other disease that might better explain symptoms and signs in the patient
- Any condition that might interfere with cranial MRI including gadolinium-DTPA application or other relevant examinations
- Vitamin D supplementation >500 IU/day within 6 months prior to randomization.
- History of allergic reaction to colecalciferol
- History of sarcoidosis, nephrolithiasis, pseudo hypoparathyroidism
- Relevant liver disease (incl. neoplasia, chronic hepatitis, history of liver failure, cholestasis, ALAT, ASAT > 3.5x upper limit of normal, bilirubin > 2.0 mg/dl
- Renal or bone marrow dysfunction defined by hemoglobin < 8,5 g/dl, WBC < 2,5/nl platelets < 100/nl, creatinin clearance (Cockroft-Gault) < 110ml/min (males) and < 95ml/min (females)
- Hypercalcaemia >2,7 mmol/l, urine calcium/creatinin ratio >1
- Concomitant medication with hydrochlorothiazide, digitoxin, digoxin, phenytoin, barbiturates, other vitamin D-containing preparations than study medication
- Pregnancy or lactation
- Participation in other interventional clinical trials within 3 months before or any time during the trial
- Medical, psychiatric or other condition that relevantly limits the ability of the patient to provide informed consent, or to comply with the protocol
- Lack of agreement with data protection guidelines