Dietary supplements

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Author & Year: Peikert et al, 1996[617] **Study design:** RCT **Comparison:** Magnesium vs placebo **Setting:** outpatients **Duration of follow-up:** 4 weeks baseline, 12 weeks treatment	**Patient group** Adults meeting IHS criteria for migraine with or without aura **Inclusion criteria:** Patients aged 18-65 years IHS criteria for migraine with or without aura **Exclusion criteria:** Pregnancy or nursing, known ammonium-phosphate-calculus-diastheses, kidney function disorders with serum creatinine higher than 1.5 mg/dL, other interfering medical disorders, known allergies to any of the components of the preparations, serious psychiatric diseases, tendencies towards substance-dependent or abusive behaviour, and inability to distinguish migraine from other headaches. **All patients** **N:** 81 **Group 1** – Magnesium [mean, SD] **N:** 43 **Age (mean):** 43.8 (10.7) **Drop outs:** 7 **Duration since onset (month):** 203.2 (130.8) **Frequency of attacks/ 4 weeks:** 3.63 (1.76) **No of days with migraine/ 4 weeks:** 4.95 (2.69)	**Group 1 600mg (24 mmol) magnesium** (trimagnesium dicitrate magnesium diasporal, Germany) water soluble granular powder every morning **Group 2 - magnesium free placebo powder** for 12 weeks	**Change in patient-reported migraine days** Mean (SD) Group1 n=43 Group 2 n=38	**Group1:** -2.49 (0.05) **Group 2:** -1.16 (3.89) **p value:** 0.04	**Funding:** NR **Limitations:** **Additional outcomes:** More than 50% reduction in migraine days **Notes:** Analysis carried out on ITT population, apart from responder rate outcome which was undertaken on PP analysis. All figures are mean reduction-no baseline and final values available). No prophylaxis 3 months prior to study. Acute medication allowed (monotherapy and polytherapy, including acetylsalicylic acid, sumatriptan, metoclopramide, simple analgesics + codeine, ergot + caffeine).
			Change in patient-reported migraine intensity (intensity of attacks recorded on VAS) Group1 n=43 Group 2 n=38	**Group1:** -2.06 (2.77) **Group 2:** -1.25 (2.29) **p value:** 0.3199	
			Change in patient-reported migraine frequency mean (SD) Group1 n=43 Group 2 n=38	**Group1:** -1.51 (2.07) **Group 2:** -0.58 (2.30) **p value:** 0.0303	
			Responder rate (50% reduction in migraine days) Group1 n=36 Group 2 n=32	**Group1:** 19/36 (52.7%) **Group 2:** 11/32 (34.4%) **p value:** 0.149	
			Change in use of acute pharmacological treatment Group1 n=43	**Group1:** -5.07 (6.58) **Group 2:** -2.40 (6.59) **p value:** NR	

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	Duration of attacks (days): 1.42 (0.76) **Severity of attacks (VAS):** 6.02 (1.87) **Group 2 - Placebo** **N:** 38 **Age (mean):** 47.6 (10) **Drop outs:** 6 **Duration since onset (months):** 181.6 (125.5) **Frequency of attacks/ 4 weeks:** 3.66 (1.71) **No of days with migraine/ 4 weeks:** 5.47 (3.19) **Duration of attacks (days):** 1.66 (1.22) **Severity of attacks (VAS):** 6.35 (1.92)		Group 2 n=38 (Mean reduction Per patient, (number of single doses)) **Incidence of serious adverse events** Patients dropped out due to AE	 **Group1:** 3/43 (7%) **Group 2:** 0/38 **p value:** NR	

Abbreviations: NR=not reported, M/F=male/female, N= number of patients, SD=Standard deviation, SE=Standard error, ITT=Intention to treat analysis, PP=per protocol, CI=confidence interval, AE=adverse event, IHS=International Headache Society, VAS=visual analogue scale

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Author & Year: Schoenen et al, 1998[706] **Study design:** RCT **Comparison:** Riboflavin vs Placebo **Setting:** NR **Duration of follow-up:** 1 month baseline then randomised to 3 months treatment	**Patient group:** Adults with, migraine with or without aura defined by IHS **Inclusion criteria:** Patients aged 18-65 years, migraine with or without aura defined by IHS. History of migraine at least 1 year, between 2 and 8 attacks per month, had no more than 5 days of interval headaches per month, had no analgesic or ergotamine over-consumption, no serious organic or psychiatric disease. Women required to have adequate contraception. **Exclusion criteria:** NR **All patients** **N=** 54 **Group 1 – Riboflavin** [mean, range] **N:** 28 **Age (mean):** 36.9 (18-62) **Drop outs:** 1 **No of women:** 21 **Attack frequency (/month):** 3.83 (2-6) **Attack duration (hr):** 35.42 (6-84) **Migraine history:** with aura: 23, without aura: 1, both: 4 **Disease duration:** 11.8 (1-40) **Group 2 - Placebo**	**Group 1 Riboflavin** – oral 400mg (Riboflavinum D 2914A, Federa, Brussels) **Group 2 – Placebo** (Avicel RC 581 850mg + betacarotene 0.4733 mg)	**Change in patient-reported headache frequency** Median (5th -95th percentiles) Group 1 n=28 Group 2 n=26	**Group1:** -2.0 (-.4, 1) **Group 2:** 0 (-2.0, 2.0) **p value:** 0.0001	**Funding:** Belgian Migraine society **Limitations:** Uses headache days and migraine days interchangeably. **Additional outcomes:** None **Notes:** Randomised in 10 blocks of 10 packages, each block comprised 5 placebo and 5 active treatments. All figures for outcomes are medians No baseline and final values available- only change values. p values Mann Whitney U test, Fisher's exact test (two tailed) for responder rate. Four point scale used to determine severity of migraine. Patients took acute medications including oral or rectal analgesics with antiemetics, oral or subcutaneous sumatriptan, and some took ergotamine-containing preparations. *calculated by NCGC
			Change in patient-reported headache days Median (5th -95th percentiles) Group 1 n=28 Group 2 n=26	**Group1:** -3.0 (-9.0, 1) **Group 2:** 0.50 (-5.0, 7.0) **p value:** 0.0001	
			Change in patient-reported headache intensity Severity- four point scale, Median (5th - 95th percentiles) Group 1 n=28 Group 2 n=26	**Group1:** 0 (-2.5, 0.43) **Group 2:** 0.05 (-1.0, 1) **p value:** 0.031	
			Responder rate 50% reduction in migraine days Group 1 n=28 Group 2 n=26	**Group1:** 17/ 28* (59%) **Group 2:** 4/26* (15%) **p value:** 0.002	
			Use of acute pharmacological treatment Per migraine day	**Group1:** 0 (-1.67, 1.25) **Group 2:** 0 (-0.75, 1.30)	

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	N: 26 **Age (mean):** 35.2 (19-53) **Drop outs:** 3 **No of women:** 21 **Attack frequency (/months):** 3.71 (2-7) **Attack duration (hr):** 32.35 (6-72) **Migraine history:** with aura: 19, without aura: 2, both: 5 **Disease duration:** 13.9 (1-47)		Median (5th -95th percentiles) Group 1 n=28 Group 2 n=26	**p value:** 0.369	

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