Vitamin A Trial For Retinitis Pigmentosa

Introduction: A randomized, controlled clinical trial to determine whether vit A alone or vit E alone or in combination have a beneficial affect on RP.

Eligibility:

1. ≥20/100
2. Goldman better than 8° (central with V-4-e).
3. ERG amplitude of 2.5 µV or greater to 0.5-Hz white or
4. ERG amplitude of 0.12 µV in response to 30-Hz in one eye
5. 18 to 49 years old
6. Excluded if atypical forms of RP
7. Excluded of weight <5 %ile

High serum vit A or vit E or high dietary intake of either

Outcome measured:

1. ERG
2. VA
3. VF

Methods:

ETDRS acuity charts.
Kinetic VF with V-4-e
ERG with bipolar contact lens: Mixed cone & rod response & cone (flicker)

Treatment:

Group 1: vit A 15000 IU/d plus vit E 3 IU/d
Group 2: vit A 75 IU/d plus vit E 3 IU/d
Group 3: vit A 15000 IU/d plus vit E 400 IU/d
Group 4: vit A 75 IU/d plus vit E 400 IU/d

Mean follow up was 5 years.
Separate cohort of better ERG responders to be able to measure decline or effect. “Higher amplitude cohort”

Results:

Rate of ERG amplitude decline per year

Vit A	6.1%
Trace	7.1%
A+E	6.3%
vit E	7.9%

Rate of decline ERG amplitude per year “higher amplitude”

vit A	8.3%
Trace	10%
A+E	8.8%
Vit E	11.8%

Failure was defined as 50% or more decline from base line by year.

Survival fractions

Relative risk

vit A 0.68% (32% less likely to "fail")

vit E 1.42% (42% more likely to fail)

@6 years % of those surviving (ie not having a 50% reduction in baseline ERG)

vit A 62%

trace 48%

A+E 50%

vit E 27%

More vit A you took the slower the decline.

VF area loss per year

Vit A	5.6%	6.3% (higher amp ERG)
Trace	5.9%	7.2%
A+E	6.2%	7.3%
Vit E	6.3%	7.8%

Declines in ETDRS VA per year

Vit A	1.1 letters/year
Trace	0.9
A+E	0.7
Vit E	0.7

ERG amplitude was related (significantly) to patient driving during day or night, walking unaided at night or being presently employed.

Conclusions:

1) Patients receiving vit A 15 000 IU/d had a significantly smaller average rate of loss of remaining ERG amplitude per year than those that did not.
2) Vit E may have an adverse affect on the course of common RP.